United States
of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE *110th* CONGRESS, FIRST SESSION

Vol. 153 WASHINGTON, WEDNESDAY, MAY 2, 2007 *No. 71*

Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland.

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Our Father in heaven, light of the world, give the Members of this body Your light. Shine Your light to help them see the truth. Shine Your light so they can see the path You desire them to travel. Shine Your light so they can see themselves as they truly are and not take for granted the freedoms they enjoy. Shine Your light so they may live expectantly, open for what You will do or give. Shine Your light so they may see You in all Your majesty and love. Lord, fill this Chamber with the light of Your presence, enabling each Senator to discern and do Your will.

We pray in Your radiant Name. Amen.

PLEDGE OF ALLEGIANCE

The Honorable BENJAMIN L. CARDIN led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
Washington, DC, May 2, 2007.

To the Senate:

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland, to perform the duties of the Chair.

ROBERT C. BYRD,
President pro tempore.

Mr. CARDIN thereupon assumed the chair as Acting President pro tempore.

RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

SCHEDULE

Mr. REID. Mr. President, the Senate will now begin a 60-minute period of morning business, the majority controlling the first half, Republicans controlling the final portion. Following the usage of all morning business, we will resume consideration of S. 1082, the FDA authorization legislation.

Yesterday, Senator DORGAN offered an amendment relating to drug reimportation. A cloture motion was filed on that last night. The cloture vote will occur tomorrow morning. Amendments in the second degree to the Dorgan amendment would have to be filed 1 hour prior to the cloture vote. I hope other Members who have amendments will file them as quickly as possible, to work with the managers. We have Senators KENNEDY and ENZI who are handling the legislation. They have a good relationship. They have done a lot already on this complicated legislation.

Yesterday, I indicated to the staff on both sides of the aisle that it may be necessary to have votes as early as noon on Monday. I hope we can finish the FDA bill tomorrow. If we can, then likely there would be no votes and we would move to other legislation, which would be WRDA, which has passed the House overwhelmingly. It came out of committee under the guidance of Senators BOXER and INHOFE, and we should be able to finish that bill next week.

Immigration is still on line to come up in the last 2 weeks of this work period. Next Wednesday, a week from today, I will rule XIV legislation that will put us in line to move to this during the last 2 weeks of this work period. It is legislation that is badly needed. We have had numerous meetings of Democratic and Republican Senators that have been going on for about 3 months. Progress has not been as we anticipated on either side, but we are going to move to this. Something has to be done. If we don't complete this legislation over here, then it certainly won't be done this year. Next year, a Presidential election year will make it very difficult. The three areas, of course, that are of concern are border security, and it is necessary that we visit that to see what can be done; with temporary workers, a pathway to legalization for the 12 million people who are here with bad paper; then we have to finally make sure we do something to make sure the employer sanctions aspect of the law is meaningful. At the present time, it is not. We have a lot to do there. I have had conversations with Senator KENNEDY, Senator LEAHY, and a number of other interested Senators over the last several weeks, including Senator KYL and others on the Republican side.

Mr. President, the President did veto the spending bill we sent him last night. It is unfortunate, but he did veto it. There will be a veto-override vote in the House tonight, it is my understanding.

The first piece of legislation dealing with another bill to send to the President will come to us from the House. I have had a number of consultations with Speaker PELOSI. At this stage, we are going to wait and see what happens at the White House today. The ball is in the President's court. He has to come forward with something that is satisfactory to Democrats and a significant number of Republicans.

There has to be some change of direction in the war. We find ourselves in

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the middle of a civil war where hundreds and hundreds of people are being killed each week, where we are losing soldiers at a rate that is untoward even in this war. Last month was the highest casualty rate this year. In the 51 months of the war, it is one of the highest casualty rates. So it is something for which we have to carry the wishes of the American people into legislation and change this war and bring our troops home.

RESERVATION OF LEADER TIME

The ACTING PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The ACTING PRESIDENT pro tempore. Under the previous order, there will now be a period for the transaction of morning business for up to 60 minutes, with Senators permitted to speak for up to 10 minutes each, with the first half of the time under the control of the majority, the second half of the time under the control of the Republicans.

The Senator from Washington is recognized.

EMERGENCY SUPPLEMENTAL APPROPRIATIONS

Mrs. MURRAY. Mr. President, we are now in the fifth year of the war in Iraq. Once again this year, the President failed to include an honest cost of the war in the budget he sends to Congress every year. Why is that so important at this time? If the President had initially sent to Congress a realistic budget instead of one that is intended to make his fiscal policies look less irresponsible, our men and women in the service wouldn't be faced with debate after debate after debate on emergency spending bills to pay for the cost of the war. Unfortunately, again, he did not send us a budget that was honest and paid for the war. So what we have now is an emergency spending bill for Iraq and other emergencies.

Unfortunately, last night—and sadly, in my opinion—the President decided to say no to our men and women in Iraq, to our veterans, to victims of Katrina, and to many other people who needed this measure passed and signed by him.

Democrats understand that our troops and their families should not pay for the President's budget games. That is why we passed funding for the emergency supplemental at record speed—faster, in fact, than the Republicans did in the last 2 years. Back in 2005, the Republican Congress didn't send the President emergency funding until May 10. In 2006, the Republican Congress did not send an emergency funding bill until June 15. Not only did we send the White House a bill earlier than ever, we sent legislation that contained more funds than the President requested and all the money our troops need. Unfortunately for our troops, yesterday, 4 years after President Bush declared ''mission accomplished'' and 12 days after it was reported that 104 American servicemembers died in April, making it the deadliest month since the surge began, the President decided to veto that bill. With that, he decided to delay the funding for our troops.

Included in that bill were billions of dollars to help solve the problems facing our men and women in uniform when they return home. The President didn't ask for those critical dollars. In fact, he has never included our wounded warriors as a cost of the war. Their families and now both Houses of the Congress understand the obligation to our heroes and have included them as a cost of war in this bill.

The bill we sent to the President provided money to improve Walter Reed and other VA facilities that we know are in disrepair and money to help increase access to medical and mental health services for our returning soldiers. More than $143 million was included to improve the VA's polytrauma center, which, among other things, would have helped the VA better diagnose and treat the increasing number of traumatic brain injuries which have emerged as a signature wound of this war.

The legislation also provided $100 million for the VA to target areas where mental health care is lacking. According to the VA's own statistics, more than 35 percent of returning Iraqi and Afghani veterans who have sought care have done so for mental health problems. We provide the funds in the bill we sent to the President. Unfortunately, he said no.

Additionally, we put in $61 million for hiring and training of new compensation and pension claims adjudicators. That is important money because we are hearing from far too many of our returning soldiers that it is taking them months to get the benefits they have earned. These new claims processors will help address that growing backlog of claims. Unfortunately, last night the President said no.

What we have today for our veterans, 4 years after President Bush declared ''mission accomplished,'' he decided to veto this bill. He decided to delay funds that would have addressed the problems facing our veterans.

Not only did Democrats send the President funding earlier than ever, we listened to the military leaders, we listened to the Iraq Study Group, and we listened to the American people and included a provision to redeploy our forces from the Iraqi civil war. Americans overwhelmingly oppose the President's escalation plan. General Abizaid, General Casey, and other top former officials have made clear that a surge will not be a solution to a civil war in Iraq. Reportedly, the Joint Chiefs of Staff were not in favor of escalation, and even Colin Powell opposes the escalation. In fact, Colin Powell, who we know saw combat in Vietnam, said:

> I am not persuaded that another surge of troops into Baghdad for the purposes of suppressing this communitarian violence, this civil war, will work.

GEN John Abizaid, former commander of U.S. Central Command, said:

> I do not believe that more American troops right now is a solution to this problem.

The Iraq Study Group, made up of Republicans and Democrats, called for the redeployment of our forces. But the President ignored all of them. He decided instead to escalate the number of troops in Iraq.

This escalation is in its third month, and so far the results are not promising. The Iraqi Government reported that violence from February to March increased. Officials said the number of car bombings in Baghdad is rising. According to the U.N., sectarian violence in the capital has not declined one bit. Officials have also reported that sectarian violence outside the capital has increased. As I mentioned, 104 American troops died in April—the deadliest month since this surge began.

The redeployment provision this Democratic-led Congress included in the bill provided the President with an opportunity to force Iraqis to finally take responsibility for their own country. We are in the fifth year of this war, and Iraqis have yet to stand up for themselves. They are not policing their own streets. They are not running their own army. Their Government is a mess. Something has to be done to show them they have to get their act together, they have to take ownership of their own future.

That is what the redeployment provision did in our bill. It said to Iraqis: After 5 years—5 years—and thousands of U.S. lives, you have to take responsibility for your future. It said: You must stand up.

Well, unfortunately, for America's security, 4 years after President Bush declared ''mission accomplished,'' and after we have lost 3,351 troops, the President, last night, vetoed the bill. By doing so, he ignored calls from military experts and the American people for redeployment and the need to make clear to the Iraqis they have to take responsibility for their own future.

The President asked our Nation for patience after the first and second years of this war. Then he asked the American people for more time after the third year, and more time after the fourth year.

This year, the fifth year of the war, he is now again asking us for patience, for the American people to just stand by as more of our young men and women die and as the Iraqis continue to shirk their responsibility for their own country.

It is clear our troops are now policing an open-ended civil war. Now, more than ever, we need a new direction in Iraq. Unfortunately, yesterday, and, sadly, the President vetoed a bill which

did provide a way forward. In doing so, he withheld millions of dollars for our troops and for our veterans and ignored the advice of military leaders and the Iraq Study Group and, importantly, the will of the American people.

Today the President stands alone against the vast majority of Americans desperately seeking a new direction in Iraq. It is now up to him to come to the negotiating table and provide the American people with a real strategy for success.

Mr. President, we also have before us today a bill on the FDA.

Can I ask how much time I have remaining?

The ACTING PRESIDENT pro tempore. The Senator has only about a half a minute remaining.

Mrs. MURRAY. Mr. President, I see another colleague on the Senate floor, and I ask him how much time he is going to need.

Mr. BROWN. Five or ten minutes. Go ahead.

Mrs. MURRAY. Mr. President, I ask unanimous consent for an additional 5 minutes to speak to the FDA bill that is in front of us today.

The ACTING PRESIDENT pro tempore. Without objection, the Senator is recognized.

FDA REAUTHORIZATION

Mrs. MURRAY. Mr. President, all of us in the Senate share the same goal of making sure the Food and Drug Administration stays as the gold standard for drug safety and effectiveness, and the legislation that is before the Senate today moves us toward that goal.

Throughout our country, researchers, scientists, and doctors are making 21st century medical advances, and the legislation we are looking at will ensure we have a 21st century FDA. It provides the resources, the authority, and the oversight to ensure that safe drugs move from the lab to our medicine cabinets without delay.

Like other Members of the Senate, I worked on the FDA reforms back in the 1990s. Those reforms responded to the challenges we faced then. The bill before us now responds to the challenges we face today.

In recent years, we have seen a lot of problems at the FDA with drug approval and postmarket surveillance. The bill we have addresses those challenges and ensures the FDA has the resources and the tools to promptly and thoroughly review new drugs and medical devices.

The bill reauthorizes and improves two pieces of legislation that will be critical in providing a timely review process. It creates a new system to actively monitor drugs after they have been approved by the FDA. It strengthens science at the FDA and, importantly, improves transparency. It improves oversight and information about clinical trials, and it works to prevent potential conflicts of interest among advisory committee members.

Like many Americans, I was shocked at the recent revelations concerning drugs that posed risks to public safety but remained on the market for far too long. This legislation moves to address those concerns by instituting strong, new protections, including postmarket studies that will be made available to the public. I believe this new transparency and vigorous oversight is the right path toward restoring public confidence in the FDA.

The bill takes critical steps also to improve medical care for our children. The Best Pharmaceuticals for Children Act that is included in this bill uses incentives and regulations to put America's children first. It builds upon the legislation we enacted back in 1997 that ensures pediatric medicine is a priority and that information on pediatric drugs is readily available. It extends and improves a program that has undertaken nearly 800 studies and has helped to provide pediatric labeling information for 119 drugs.

The Pediatric Research Improvement Act included in this bill is another critical component of improving pediatric care. It provides needed safety measures through mandatory clinical trials. It will help to continue pediatric oversight programs that have required trials for more than 1,000 pediatric drugs since 1998. All too often, doctors are not given guidance on the proper dose of prescription drugs for children. This bill is going to eliminate that guesswork so our children get the right doses for safer, more effective treatment.

The bill also provides help to our Nation's children through the Pediatric Medical Devices Safety and Improvement Act. Every year, we see these wondrous technological improvements in medical devices. However, sometimes those improvements do not account for the needs of the children and the pediatricians who treat them. What that means is essential, often lifesaving devices do not meet the size or the scope or the needs of sick children. This bill will push manufacturers to develop and produce devices that are safe and effective for children and infants. Through incentives and investor outreach, this bill will ensure that exciting advances in lifesaving devices are not just limited to adults.

This legislation also delivers greater safety while providing better access. I believe it will improve the way we deliver safe innovative health care in America, and it is really my hope it will also begin to restore confidence in the institutions that safeguard our public health.

The American public deserves nothing less than the gold standard of care from our FDA. When a nervous parent or worried senior visits their corner pharmacy, they deserve to know the product they buy on that shelf has been approved by a thorough and complete process. When a patient begins to take a new drug, they deserve a system that has actively tracked that drug and provides the patient with information on any risks they might face. Everyone—drug companies, researchers, patients, and doctors alike—deserves a system that supports an efficient and timely FDA approval process.

So I am very eager to move this legislation forward and get it to a vote so we can begin to deliver what the American people deserve. I hope this Senate moves quickly on this bill and we are able to move it along in the process very shortly in the Senate.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Ohio is recognized.

TRANSEA ACT

Mr. BROWN. Mr. President, our trade policy is fundamentally flawed. Years of wrongheaded trade pacts have sent millions of jobs overseas, devastated our communities, and opened our Nation too often to serious homeland security concerns.

When we open our borders to trade, as we should, we open them to national security threats. Congress must assure the American people we have done everything within our power to protect their safety and their health and their welfare and to promote fair trade.

It is estimated that less than 10 percent of foreign cargo is inspected before entering our country. We must both ensure that our ports are operated securely and with clear lines of accountability, unlike the deal to transfer operation of six U.S. ports to a state-owned company controlled by the United Arab Emirates that this administration approved just last year.

The decision to allow a UAE-controlled company to run our ports had significant national security implications. The UAE was, and still may be, a financial and travel outlet for known terrorists. It was not until leaders in both parties in the Senate and in the House of Representatives called attention to this enormous blunder that this deal was stopped.

It is imperative Congress take steps to ensure our homeland security needs are secured every bit as much as our economic well-being.

Today, I am introducing, with Senator BYRON DORGAN of North Dakota, the Trade-Related American National Security Enhancement and Accountability, TRANSEA, Act.

This act requires the Office of the United States Trade Representative, in collaboration with the Departments of State, Homeland Security, and Justice, to submit a report to Congress detailing the national security considerations of proposed trade agreements prior to commencing and after concluding those trade negotiations.

The bill also requires future trade agreements negotiated by the administration to include a national security waiver that allows the President to suspend any terms of the agreement should it be required in the interests of U.S. national security.

Lastly, as a final safeguard, the legislation creates a new Congressional Executive Commission on Trade Security, requiring the appointment of Commissioners by both political parties in both Chambers of Congress.

The Commissioners will be charged with annually certifying that the terms of the free-trade agreement do not pose a threat to our Nation's national security interests. Should the Commission find that compliance with the agreement would pose a threat, the President will be obligated to exercise his or her waiver to the extent necessary to ensure the safety and the security of the United States of America.

In a post-9/11 world, U.S. economic policy can simply no longer be viewed in the narrow scopes of bottom lines and profit margins. Homeland Security Secretary Michael Chertoff said, in 2006:

> We have to balance the paramount urgency of security against the fact that we still want to have a robust global trading system.

We can do both. It is the responsibility of our Government to ensure that while opening markets for our exporters, as we should, our first priority remains the safety and the security of the American people.

Mr. President, I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. ISAKSON. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The Senator from Georgia is recognized.

IRAQ

Mr. ISAKSON. Mr. President, I rise today to address the war supplemental which was vetoed last night at 10 minutes after 6 by the President. It is my understanding that today leaders from both sides of the Senate will go to the White House, this afternoon, to begin talking about where we go next.

I rise today to talk a little bit about what has got us to where we are, why we are where we are, and what, in my judgment, as one Member of the Senate, we need to be focused on.

I am glad the President vetoed the war supplemental with timelines for withdrawal. It is absolutely wrong to tie the money to support our troops to arbitrary timetables that have nothing to do with success or failure but only to do with the declaration of a cause being lost. We should never declare, as Members of the Senate, our cause to have been lost. And we should never hold hostage the money for our troops based on arbitrary deadlines or thresholds.

It is, however, important for us to debate the war on the floor of the Senate. I hope when the next supplemental comes, it will be a supplemental that goes to support our men and women who have been deployed in defense of freedom, to give them everything they deserve and everything they need without strings and complication. To do so will not keep us in the Senate from debating the war, but it will clearly separate the money to support our troops from whatever the course that debate may take.

We have a long history in this country of many great Americans taking exactly the same position. One of those great Americans, Walter George, a Member of the Senate, from Georgia, a Democrat, in 1955—when Dwight Eisenhower was President of the United States of America and Adlai Stevenson had been his first opponent, and would be his second opponent in the 1956 Presidential election—the big issue of the day was the issue of Quemoy and Matsu and Red China's attempt to expand its influence on those islands and the policy of the United States of America and our President, Dwight Eisenhower. In Time magazine, April's issue, 1955, Walter George, Senator, Democrat from Georgia, a man in whose legacy and in whose shadow I now serve, said the following:

> If it would advance the cause of peace, I would be happy for the President to declare his policy. But how would it advance the cause of peace to inform the enemy of what we intend to do?
>
> I know one thing—

George said, and I continue to quote—

> if we do fulfill our high mission and our high destiny, it will be because we have resolved to do our dead level best to advance peace, to advance security, to shore up a shaky world. Only by doing that can we vindicate the sacrifice of those who died on land and at sea, and fulfill the hopes of men and women in every free land.

It has been 52 years since that statement was made, but it could never ring more true than it rings today. Walter George was absolutely right, and Walter George, a Democrat, came to the defense of Dwight Eisenhower, a Republican who was President, when Dwight Eisenhower was being forced to play our hand in a critical issue of the day. We should never force our chief executive officer, nor should we force our generals, nor our troops in the field, by declaring our hand before the cards are dealt.

There are a few other quotes I wish to share with my colleagues as I lead up to the point I want to make this morning, and these are contemporary quotes and these are quotes about Iraq. These are quotes about the supplemental. These are quotes about our brave men and women in harm's way. The first is by General Lynch, the commanding officer of the third ID. When asked about whether funding should be tied to an arbitrary timetable for withdrawal, he said:

> Ultimately, a precipitous withdrawal would increase the probability that American troops would one day have to return to Iraq and confront an enemy that is even more dangerous than today.

He is absolutely correct. Every time this country waited or every time it determined to withdraw from a conflict or looked the other way from a challenge of evil, it only had to muster itself in greater numbers and fight with greater losses at a greater day in the future.

General Lynch continued:

> No matter how frustrating the fight can be and no matter how much we wish the war was over, the security of our country depends directly on the outcome in Iraq. The price of giving up there would be paid in American lives for years to come. It would be an unforgivable mistake for leaders in Washington to allow policies and impatience to stand in the way of protecting the people of the United States of America.

I could not say it better myself.

Lastly, for quotes from contemporaries, Gary Kurpius, commander of the Veterans of Foreign Wars, said the following:

> The time to debate the war is not in front of a microphone making irresponsible statements, and it's certainly not in the funding bill that keeps our troops alive. If our troops need funds, it is the responsibility of Congress to provide them the money. Debate the war elsewhere.

My last quote is from an e-mail I got from Captain Schratt, on the ground with the U.S. Army in Baghdad right now, a couple of weeks ago when this debate was going on. He e-mailed me and said: I see they are debating whether or not they can not support the war and still support me. He said: Please tell them I am the war.

That is the truth. Our troops are the war. They are deployed and they are fighting and their funding should not be restrained or constrained or in any way hinged on political gymnastics. Those gymnastics belong in the speeches on this floor and the dialogue we have with our administration.

Now, it is my understanding there are some who are talking about a second supplemental to come, to be an incremental supplemental, maybe 60 days at a time. I would implore the Senate to consider not doing that because that brings uncertainty to our troops in the field and only partial funding on a daily or on a 60-day basis, which is wrong. There are others who are talking about maybe benchmarks—not timetables for withdrawal but benchmarks for the achievement of the Iraqi people. That may or may not be wise, depending on what those are, and I will reserve judgment, but I will tell my colleagues one thing. A lot of us around here have selective memories and have forgotten the fact that we have had some benchmarks.

In fact, when we went into Iraq, the President of the United States, George W. Bush, declared three succinct benchmarks. He said: When we deploy our troops, we will do the following: A, we will search and find the weapons of mass destruction that the U.N. and the entire world believed were there, and in fact we found the remnants and the evidence, although never the smoking gun. Then, second, he said: We are

going to give the Iraqi people a chance to hold free elections and determine a new Constitution and self-determine their future. The Iraqis have held three elections. They have a parliament. They have established a self-determined democracy in their way of doing so, and it is functioning. Then the President said: Our third goal will be to train the Iraqi Army so that it can protect and defend that fledgling Government and we will come home.

Those are three benchmarks. Two of the benchmarks have been achieved. The third benchmark is what the surge is intended to accomplish.

Today in downtown Baghdad and in Anbar Province, American troops are sleeping and eating and deployed in the neighborhoods—not in bases—side by side with Iraqi troops. The securing of neighborhoods is taking place, the holding of neighborhoods is taking place, and the rebuilding of those neighborhoods is soon to follow. In the months ahead, if we remain committed to the cause, if we fund our troops, we have the opportunity to reduce the violence, to allow the reconciliation that is so necessary.

So as people debate whether we ought to put benchmarks in supplemental appropriations for our men and women in harm's way, I hope they will recognize we have benchmarks, three that we established when almost every Member of the Congress voted to go into Iraq, two of which have been completely met and satisfied and a third is partially there and will ultimately be achieved if we don't pull the plug and we continue to fund our troops.

War is never fun and it is always controversial. There is not a one of us in this room who does not wish war was ever necessary. But we know as we look back upon history, as Walter George, the Senator from Georgia, said: We have to honor the lives of those who were lost on land and sea to preserve freedom and liberty and democracy for the people of the United States of America. We are at such a day today with our battle in Iraq and in the overall war on terror. Iraq is but a battle in that war. We don't need to send signals that we will quit; we don't need to declare that we have lost. We need to declare the resolve to see the mission through. There are 140,000 brave men and women deployed in Iraq right now committed to the cause. When they come home and I talk to them, to the man and to the woman, they all say: We are there for the right reason. We are making progress. Continue to support me, and we will do the job.

So as the leaders go to the White House today to discuss with the President where we go next, as we look to what we do in this supplemental, let's resolve to fund our troops. Let's resolve to do it without condition on our troops. Let's resolve to do it without declaring defeat but instead in the interest of and with a commitment to victory. Then, if we have debate—and we should and we must—let's have it on the floor, unattached to funding, not restricting our troops but deciding what our course will be and the absolute objective to be, rather than a conditional debate that only sends a message to our enemy that our resolve may be lost and we may be turning the other way. As Walter F. George said in 1955, an American Democratic Senator from Georgia, in support of a Republican President, we should honor the lives that have been lost and stay true to our commitment, and it will never be in our interests to declare to our enemies what our intentions might be.

Mr. President, I yield the floor, and I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. CORNYN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. CORNYN. Mr. President, 3 months ago, the President of the United States asked Congress to pass an emergency war spending bill that would provide our brave men and women in uniform with the funds and the flexibility they need to succeed in what has been called the central front on the war against al-Qaida in Iraq. Instead, this body helped pass a bill that substitutes the opinions of politicians for the judgment of our military commanders. The bill Congress passed was, in my view, unacceptable, and late. Eighty-five days after the President had requested the funds on an emergency basis, Speaker PELOSI finally forwarded the bill to the President yesterday. It was no surprise that the President vetoed the bill within hours because he had said he would, and so the outcome was predictable.

The President, in his address to the Nation last night, made it very clear that it remains his desire to work with Congress to resolve this matter as quickly and expeditiously as possible. Today, he is holding a bipartisan meeting with congressional leaders at the White House for that purpose.

We have known for weeks that this legislation was flawed and that we would find ourselves in this place—a bill that included a surrender date, when we tell our enemies we would simply give up, and one larded with porkbarrel spending in order to secure the votes of recalcitrant Members who were unwilling to vote for this flawed bill on its merits.

The President outlined these shortcomings last night.

First, he said the bill would mandate an artificial deadline for troops to begin withdrawing from Iraq. The withdrawal could start as early as July 1 and would have to start no later than October 1 regardless of the situation on the ground. The language in the bill defies sound military logic and, I would say, common sense itself. It makes no sense to tell the enemy when you plan to start withdrawing. Setting a deadline for withdrawal is setting a date for failure, and it would be irresponsible. As the President made very clear last night, setting this deadline for withdrawal would also demoralize the Iraqi people and encourage the killers across the broader Middle East, such as al-Qaida, and send a signal that America will not keep its commitments.

Second, the bill would impose impossible conditions on our commanders in combat. After forcing most of our troops to withdraw, the bill would dictate the terms on which the remaining commanders and troops could engage the enemy. American commanders in the middle of a combat zone would have to take fighting directions from politicians thousands of miles away in Washington, DC.

Third, as I mentioned, the bill is loaded with billions of dollars of nonemergency porkbarrel spending that has nothing to do with fighting the war on terror and which demeans the importance of this particular legislation, designed as it is to support our troops who are literally in harm's way.

Democratic leaders know that many of us in Congress disagree with their approach and their desire to use this bill as an opportunity to make a political statement about their opposition to the war. Yet we know there are not enough votes to override a veto. It is time to put politics behind us and support our troops with the funds they need. Some have confused the need to debate, which I agree with, with cause for delay, which I disagree with. There should be no cause for delay in getting these emergency funds to our troops, and the debate will indeed continue.

In February, we began sending the first of the reinforcements that General Petraeus, the new commander in Iraq, requested. Not all of these reinforcements have arrived; roughly half of them have. As General Petraeus said just last week, it will be at least the end of the summer before we can assess the impact of this new operation, the Baghdad security plan, or surge. We ought to give General Petraeus's plan a chance to work.

In the months since our military has been implementing this plan, we have actually begun to see some important results. General Petraeus noted that one of the most important indicators of progress is the level of sectarian violence in Baghdad. He reported that, since January, the number of sectarian murders has dropped substantially. Spectacular suicide attacks that have caused great suffering in Iraq continue because these attacks are largely the work of al-Qaida, the Sunni extremists—the enemy that everyone agrees we should be fighting, or at least some say we should be fighting. At the same time, they would impose arbitrary deadlines, imposing a surrender date on our troops.

The objective of these al-Qaida attacks is to reignite the sectarian violence in Baghdad and breaking support for the war here at home. That was the goal of al-Zarqawi, whom we were fortunate to be able to take out of the fight, and that is the fight now of the remaining al-Qaida extremists in Iraq. General Petraeus explained it this way:

Iraq is, in fact, the central front of al-Qaida's global campaign.

It just boggles my mind, Mr. President, for some of us to stand here on the floor and say we ought to withdraw our troops from Iraq when, in fact, al-Qaida—the enemy that hit innocent Americans and killed 3,000 of them on September 11, 2001—considers Iraq to be the central front in their campaign against the West. Al-Qaida's role makes the conflict in Iraq far more complex than a simple fight between Iraqis. Many also belong to the same terrorist network, as I said, that attacked us on September 11, 2001. Were we to leave prematurely, were we to leave a power vacuum in Iraq, al-Qaida would no doubt, as they did in Afghanistan earlier, use that power vacuum as an opportunity to regroup, to plan, to train, to recruit, and then to export additional terrorist attacks against the United States here on this continent.

We need to give our troops all of the equipment and training and protection they need to prevail. Without a war funding bill, the military has to take money from some other account—notably, the Air Force or Navy—just in order to make sure the Army has the resources they need, so the troops can have the equipment they need, so they can rotate back on a timely basis and come home to the loving arms of their families, to repair existing equipment. And worst of all, in one sense, failing to send this money on a timely basis to the military hurts the military families who are waiting behind, anxious, as we all understand, for the welfare and safety of their loved ones. Our troops and their families deserve better.

So I hope that after the last 86 days, which have been characterized by political theater and gamesmanship, where some have been more focused on the 2008 election and trying to find ways to gain political advantage, I hope Republicans and Democrats, the legislative branch and executive branch, can come together and do what we should have done months ago—get the funds to the troops as soon as possible, without the surrender deadline, without tying the hands of our military commanders and making their opportunity for success impossible, and without the porkbarrel spending that demeans the noble sacrifice of these brave men and women.

Mr. President, I yield the floor and yield back our remaining time.

I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. COCHRAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. WEBB). Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, we yield back all morning business time.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Landrieu amendment No. 1004, to require the Food and Drug Administration to permit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella.

Dorgan amendment No. 990, to provide for the importation of prescription drugs.

AMENDMENT NO. 1010 TO AMENDMENT NO. 990

(Purpose: To protect the health and safety of the public)

Mr. COCHRAN. Mr. President, I send an amendment to the desk and ask that it be stated.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Mississippi [Mr. COCHRAN], for himself, Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ, proposes an amendment numbered 1010 to amendment 990.

At the end of the amendment, add the following:

SEC. ___. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I am offering this amendment for myself, as well as for these cosponsors: Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ. This is an amendment to the amendment proposed by Mr. DORGAN.

Improving the health and quality of life for Americans is very important to all of us, and access to safe and effective prescription drugs is a major step in accomplishing these goals. With recent scientific advances, a number of medical therapies have been made available to treat and, in some cases, to cure diseases. We want Americans to continue to have access to safe and effective drugs that are approved by the Food and Drug Administration.

But we must not create opportunities for potentially dangerous drug products from foreign countries to reach the American consumer. For example, counterfeit products, those that have been tampered with or those of unknown origin, should not be brought into this country. I am concerned that allowing the importation of prescription drugs would allow such risks to become more likely.

The amendment proposed by the Senator from North Dakota will put in jeopardy the process we now have to ensure the safety of prescription medications and protect the health of the American people.

I am offering this second-degree amendment to require the Secretary of Health and Human Services to certify that the importation of drug products will not pose additional risks to Americans and will, indeed, lower costs to consumers.

If, as some argue, a policy of importation is safe and will reduce costs, this amendment should not be a problem.

We have debated this issue before on several previous occasions. For example, during the consideration of annual appropriations bills for the Department of Agriculture, the Food and Drug Administration, and related agencies, when considering the Greater Access to Pharmaceuticals Act, and even during the debate and passage of the Medicare Modernization Act of 2003, a similar amendment to require the safety of imported drugs was considered and unanimously approved each time.

In all these instances, the Senate has adopted this amendment by a unanimous vote. The safety of the American consumer must be our No. 1 priority. These safeguards should also be applied to this proposal.

We should be certain that any change we make in the law does not result in less protection in terms of the safety of the drugs supplied to the American people and will, indeed, make prescription drugs more affordable. Liberalization of protections that are designed to keep unsafe drugs out of this country, especially considering the terrorist threats we face now, should occur only if the necessary safeguards are in place. This amendment will ensure that the concerns of the last two administrations regarding safety and cost-effectiveness are addressed prior to the implementation of this proposal.

Counterfeiting of drugs has become a more common practice throughout the world, and the transshipment of these counterfeit products through Canada is one of the most serious dangers we face. The Canadian Government itself has said that drug products shipped to

Canada for resale in other countries do not fall under the Canadian regulatory system, and they can provide no assurance as to the safety or authenticity of such drugs.

In fact, President Bush yesterday released a Statement of Administration Policy strongly opposing any provision that allows the importation of drug products outside the current safety system of the Food and Drug Administration. The statement declares that the President's senior advisers would recommend that he veto the bill if this provision is included.

Mr. President, I ask unanimous consent that a copy of the Statement of Administration Policy be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

EXECUTIVE OFFICE OF THE PRESIDENT, OFFICE OF MANAGEMENT AND BUDGET,

Washington, DC, May 1, 2007.

STATEMENT OF ADMINISTRATION POLICY

S. 1082—FOOD AND DRUG ADMINISTRATION REVITALIZATION ACT

(Sen. Kennedy (D)–MA)

The Administration strongly supports reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). These two programs account for nearly one quarter of the Food and Drug Administration's (FDA) annual budget and support more than 2,000 Agency employees who work diligently to ensure the safety and efficacy of the medical products on which the American people rely. Reauthorizing PDUFA and MDUFMA will enhance FDA's ability to more efficiently and effectively regulate drugs, biological products, and medical devices, a critical component of the Agency's public health mission. Additionally, the Administration is committed to reauthorizing the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), which have provided invaluable information to the Agency about medical products' interaction with pediatric populations.

The Administration shares the goal of S. 1082 to provide FDA with the appropriate tools and resources to enhance the safety and efficacy of the products the agency regulates. However, the Administration has serious concerns with S. 1082 in its current form and will work with Congress to address them as the legislative process moves forward.

The Administration appreciates that portions of S. 1082 are consistent with the Administration's recommendations for reauthorization, which strengthen FDA's ability to ensure the safety and availability of new drugs and medical devices, create a new program for review of television advertisements, and strengthen post-market review. These user fee programs expire at the end of the current fiscal year, and their timely reauthorization is critical to the ability of FDA to continue to carefully and expeditiously review and approve new drugs and devices to benefit the health of the American people.

The Administration is committed to further improving drug safety through better tools for surveillance of drug events, improved scientific tools for evaluating drug safety problems, and better means of communicating drug safety problems to providers and patients. However, the Administration is concerned that the bill, as written, would require significant resources to implement burdensome process changes that will not contribute meaningfully to improving drug safety. For example, the prescriptive timeframes to develop and process Risk Evaluation and Mitigation Strategies are particularly burdensome and are not likely to contribute to improving drug safety. Additionally, the Administration is concerned about the provision in S. 1082 that would use increased user fees to fund certain additional drug safety activities that were not agreed to during the statutorily required Agency-industry negotiations. This provision reopens and is inconsistent with the Administration PDUFA proposal that was developed through extensive consultation.

There are other provisions in S. 1082 that also raise serious concerns. Specifically, the bill would make changes to the BPCA and PREA to reduce the incentives to conduct clinical trials for children, thus reducing the effectiveness of the program. It also would impose administrative burdens that would make the programs inefficient and in many ways unworkable. These provisions would reduce the flexibility the agency needs to conduct these programs, require an inefficient duplication of scientific expertise, and cause delays in the review of pediatric assessments. Both BPCA and PREA have been very successful in providing the necessary incentives for drug companies to conduct pediatric clinical trials to improve our understanding of how drugs work in children, thus enhancing the quality of their medical care. BPCA and PREA should be extended without modification.

Potential Amendments: Follow-on Protein Products and Importation of Prescription Drugs

The Administration supports the goal of making safe and effective drugs available and affordable for American consumers. While some in Congress may be interested in attaching legislation related to follow-on protein products to this bill, the Administration believes that these complex issues should be considered thoroughly through a robust scientific, regulatory, and legal discussion. Sufficient discussion has not yet occurred and should not be abbreviated for the convenience of a particular legislative vehicle. Any legislative proposal considered to authorize a regulatory pathway for follow-on protein products must, as a first priority, ensure the safety and efficacy of the resulting products, thus protecting patient safety. Furthermore, it should also include adequate intellectual property protections for innovators, in order to maintain the research enterprise that has generated life-saving medications. The Administration believes further discussion must take place before addressing these issues in legislation. The Administration strongly opposes the inclusion in this bill of any provision related to follow-on protein products.

The Administration would also strongly oppose any provision that might be added on the Senate Floor regarding the importation of prescription drugs that does not address the serious safety concerns identified in the December 2004 Department of Health and Human Services Task Force Report on Prescription Drug Importation. The Administration believes that allowing importation of drugs outside the current safety system established by the FDA without addressing these serious safety concerns would threaten public health and result in unsafe, unapproved, and counterfeit drugs being imported into the United States. As a result, if any such importation provision were included in the final version of the bill presented to the President, the President's senior advisors would recommend that he veto the bill.

The Administration strongly opposes the inclusion of any unrelated provisions that would disrupt the timely reauthorization of the user fee program. The Administration looks forward to working with Congress to reauthorize PDUFA and MDUFMA expeditiously to avoid any disruptions to these successful programs.

Mr. COCHRAN. Mr. President, these conditions contained in this amendment are the same as those the Senate has previously adopted on other occasions on other bills. I urge the Senate to again support this language and approve this amendment.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I thank the Senator from Mississippi for his cooperation. For the information of our colleagues, if we get cloture on the Dorgan amendment tomorrow, sometime prior to the expiration of the 30 hours, we will vote on the Cochran amendment. That is a notice for Members about when we will address this issue. I thank the Senator.

The Senator from Colorado raised important issues during the markup, and he has a very significant amendment to offer to the Senate. I hope we will hear from him at this time.

The PRESIDING OFFICER. The Senator from Colorado.

AMENDMENT NO. 982

Mr. ALLARD. Mr. President, I ask unanimous consent to lay aside the pending amendment, and I call up amendment No. 982.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Colorado [Mr. ALLARD] proposes an amendment numbered 982.

Mr. ALLARD. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To strike provisions related to market exclusivity)

Strike subparagraphs (D) and (E) of section 402(a)(6).

Mr. ALLARD. Mr. President, first, I thank the chairman, Senator KENNEDY, and the ranking Republican, Senator ENZI, for the bipartisan way in which they have worked in the committee, of which I am a new member. It is the HELP Committee, standing for Health, Education, Labor, and Pensions. I appreciate the opportunity to have offered this amendment in committee, as well the opportunity to offer it on the floor. It is a very important committee.

The bill, coming out of committee, can withstand some improvement. I know both Senator ENZI and Senator KENNEDY have sat down and made many changes that I think will help relieve some of the concerns we have about the bill. That is now in the form of a managers' amendment which is before the Senate.

The issue I remain concerned about is an issue that was in the original bill.

It remains in the bill, in the managers' amendment, and that is an amendment to the Best Pharmaceuticals for Children Act passed in 1997. This is an incentive program we put in place for the last decade that says to the pharmaceutical industry that if you would put some effort into getting children's medications, pediatric medications properly labeled for the market, then we will give you, in effect, an extension of 6 months on your patent rights. This has been an extremely successful program. For the life of me, I don't understand why the bill's sponsors feel it is important to put this provision in the bill.

This is a chart that reflects the drug studies that have been completed for kids, which equates to more drugs available for pediatricians to use in treating childhood diseases. As one can see, the red square on the chart is with no incentives, and very little effort was being made. But when the 6-month exclusivity provision was provided in the Best Pharmaceuticals for Children Act, we can see how dramatic the increase was and how the marketplace responded to this incentive.

In my view, we should not be removing or reducing the incentive for any pharmaceutical company to invest in children. Right now, with what the current managers' amendment has in it, it takes the 6-month exclusivity and reduces it to 3 months, and it has it applied to those that are referred to as the blockbuster drugs. In my view, I think we need to make sure everybody understands how very important this program is. If we go messing with it, we are going to reduce the incentives that are in it that have been working so well.

The Best Pharmaceuticals for Children Act allows the FDA to grant drug sponsors pediatric exclusivity. This is 6 months of additional market exclusivity—as I said, an extension basically of the patent rights—in exchange for conducting and submitting reports on pediatric drug studies. Current law is working. There is no reason I see to change significantly a program that is working.

The goal of the program is to develop additional health information on the use of such drugs in pediatric populations so they can be administered safely and effectively to children. This goal is reflected on this chart as being reached. Also, using pediatric research and development legislation to attack large pharmaceutical companies, in my view, is an abuse of power at the expense of kids. The data shows pediatric legislation has resulted in a substantial increase in pediatric prescribing information on the labels of those products, which have fulfilled the requirements necessary to be granted the pediatric exclusivity extension.

Here is what the GAO study on the Best Pharmaceuticals for Children Act has said about how the program has been working for the last decade. This study was issued on March 22 of 2007, so it is a current evaluation, and here is what they say:

> Prior to enactment of the Food and Drug Administration Modernization Act of 1997, which first established incentives for conducting pediatric drug studies in the form of additional market exclusivity, few drugs were studied for pediatric use.

Very few were done, as reflected on the chart.

> As a result, there was a lack of information on optimal dosage, possible side effects, and the effectiveness of drugs for pediatric use. Almost all the drugs—about 87 percent—that have been granted pediatric exclusivity under the Best Pharmaceuticals for Children Act have had important labeling changes as a result of pediatric drug studies conducted under this Act.

As a result, exclusivity is working. In fact, it is working so well that, in my view, with increased exclusivity we may have even had more research and development in the area of pediatric pharmaceuticals. But that issue is for another day.

My amendment doesn't request an increase in what has been working. We merely ask that we return in this piece of legislation to that exclusivity-linked period, which is 6 months, which has been working so very well under current law.

Some Members want to try to damage the blockbuster drug companies by reducing the exclusivity for those businesses, but in reality the ones who are really being hurt are our kids because we take away the number of choices a pediatrician has in providing drug therapy for those kids who could be seriously ill.

I ask my colleagues to support me in my amendment and to return us to the 6-month exclusivity and away from the 3-month exclusivity period we currently have in the managers' amendment.

Mr. President, I yield the floor.

Mr. KENNEDY. Mr. President, in a few moments we will hear from Senator DODD, who was the architect for the whole undertaking in terms of testing for children, and also for the children's prescription drug program which has been immensely successful. He deserves great credit for it. I am sure he gets a great deal of satisfaction from it. It was bipartisan, with Senator DeWine, going back many years, and certainly Senator CLINTON has added an additional dimension to this whole proposal. But Senator DODD has studied this issue very carefully, and he really is the originator of the concept. He has followed it closely, and he will speak to the Senate on this matter in a very short time.

I see my friend from Ohio on the Senate floor, who also wishes to address it, but I will just say a brief word. I believe what we have in the legislation, which was earlier fashioned by the Senator from Connecticut, is the way to go, and I would hope the Allard amendment will not be accepted.

One of the major elements in the FDA bill is the program providing incentives for developing the new drugs, and Senator DODD, Senator CLINTON, Senator ALEXANDER, and many others have been champions of this program, as was our former colleague, Senator DeWine. The reauthorization of an effective program is an opportunity to strengthen those aspects that work well and to improve those that need adjustment. Senator DODD took up this challenge and renewed the information about how the program has worked over the years since Congress last reviewed it.

He found that companies were sometimes rewarded with billions of dollars in additional sales in return for doing studies that cost them only a few million. Clearly, one must provide incentives to develop new drugs for children, but we must be responsible in doing so. That is why in this reauthorization, Senator DODD included a proposal to adjust the period of market exclusivity for drugs that generate over a billion dollars in sales. If they generate over a billion dollars in sales, these blockbuster drugs will receive only 3 months of exclusivity instead of 6 months, available to other drugs.

The Allard amendment would delete this sensible provision and give all drugs the full 6 months. That could be worth billions of dollars for a major medication. Those extra 6 months don't just apply to sales for use in children, they apply to all sales. That means a heart drug tested in children would get 6 months protection from competition, so it can wrack up big returns.

The amendment we face embodies a policy that has no proportionality. It gives the same broad protection to a drug such as Lipitor or Xanax as it does to a specialty drug that might be helpful in treating ear infections in children. Senator DODD's proposal has that sense of proportional reward, but the amendment overturns it. That is the wrong approach, and I hope the Senate will reject it.

Mr. President, I see my friend and colleague from Ohio wishes to address this issue, and I yield the floor.

Mr. BROWN. Mr. President, I thank Senator KENNEDY, and I want to join my colleagues, and I will precede Senator DODD and join him and Senator KENNEDY and others in urging a ''no'' vote on the amendment offered by the Senator from Colorado.

Drugmakers, as we know, have exclusive rights to market a prescription drug under a patent. That means no generic drugs are allowed on the market. There is no price competition and nothing to prevent drugmakers from charging top dollar for their products. Top dollar, as many of our constituents know all too well, for a prescription drug can be breathtaking. A 30-day supply of Nexium, the little purple pill, costs about $193; a 30-day supply of Exelon, an Alzheimer's drug, is $214; a 30-day supply of Pravachol, a statin drug, is $168. Under current law—under current law—drugmakers are rewarded an additional 6 months of competition-

free time on the market when they agree to evaluate a prescription drug for use in children—6 months.

That is a tradeoff. It is a tradeoff the House and Senate agreed to, where adult consumers of this drug—adult consumers of the drug—are denied a less costly generic version of, for example, Prilosec, for an additional 6 months. This means their out-of-pocket health care costs—or their employer, or their insurance company, or the government—are significantly higher than they otherwise would be. That is the tradeoff.

At the same time, drugmakers agree to conduct pediatric testing they wouldn't have done voluntarily, sometimes for reasons all their own, and those tests provide invaluable information to pediatricians for the proper use and dose of medicines prescribed to children. That was the agreement—the 6-month exclusivity agreement. That incentive has worked to increase, we all agree, the number of pediatric tests drugmakers conduct. That is important. Pediatricians now have access to new information that has enabled them to make better use of prescription drugs to help our Nation's children.

My colleague, Senator DODD, championed the 6-month exclusivity law in his efforts in this area, as did my predecessor in the Senate, and so many others, and their work has improved the lives of children. Needless to say, the Senator from Connecticut would not arbitrarily or recklessly make changes to the pediatric exclusivity law. It was his idea and his work. He clearly isn't going to compromise it. But he is recommending one change, and this amendment, the Allard amendment, undoes that change, which is included in S. 1082.

He is recommending if a drug generates more than $1 billion in revenues—that is, it is a blockbuster drug—if the drug generates more than $1 billion in revenue, that drug should receive an additional 3 months of market exclusivity instead of 6 months. The reason is both simple and compelling.

It costs about $13 million—think about these numbers—it costs about $13 million to conduct pediatric testing on a new drug. If a drugmaker is taking in $1 billion a year on that drug, $13 million is about 1 percent of their revenues on that drug. Giving that drugmaker an additional 6 months of market exclusivity on a $1 billion drug costs health care consumers and taxpayers—the taxpayers who cover the cost of public health programs such as Medicare, Medicaid, and the VA—it costs them millions of dollars each day.

This is not, as Senator ALLARD said, a provision to punish the drug companies. It is a provision to help people with their out-of-pocket drug costs. It is a provision to help taxpayers who fund Medicare, Medicaid, and the VA. It is a provision to help those businesses that are funding health care and drug plans for their employees.

The Federal Government could do it another away. The Federal Government could reimburse drugmakers for the cost of pediatric tests. It could reward them with a 600-percent profit on conducting those tests, and it would still cost appreciably less than rewarding them an additional 6 months of exclusivity. That is why we made the decision not to do it that way. But in light of the astounding imbalance between the cost of conducting a pediatric test—$13 million—and the reward that 6 months of exclusivity provides when it comes to a $1 billion drug, Senator DODD recommended we cut that in half. We provide 3 months of exclusivity for billion-dollar drugs instead.

It is still a breathtaking reward: A $1 billion drug gets a 3-month exclusivity instead of a 6-month exclusivity for a $13 million test—a breathtaking reward for one pediatric test, but it is measurably more justifiable than the 6-month moratorium on price competition.

Common sense, fiscal responsibility, and the fact that all of us in this Chamber report to U.S. taxpayers dictate that we support Senator DODD on this modest change in his own program. The Allard amendment gives $1 billion drugs a 6-month exclusivity instead of 3. The logic is, if 6 months of market exclusivity is working to prompt drugmakers to conduct pediatric testing, we shouldn't change it. By that logic, we might as well give drugmakers 100 years of market exclusivity. I am sure that would work, too.

The point is, we have to draw the line to encourage pediatric testing, which this will, and to save money for our employers, for our taxpayers, and for senior citizens' out-of-pocket costs. When a drugmaker earns hundreds of millions of dollars, in many cases out of the pockets of U.S. taxpayers, for a pediatric test that costs about $10 million, that is unnecessary, it is unjustifiable, and it is outright wrong.

Please vote for common sense, for protecting our children, for U.S. taxpayers, for consumers, and against the Allard amendment.

Mr. ALLARD. Mr. President, the Senator from Wyoming, who is managing the time, has granted permission for me to speak for 5 minutes.

Mr. President, I forgot to ask unanimous consent that the following individuals be added as cosponsors on my amendment: Senator BOND, Senator HATCH, and Senator ALEXANDER.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ALLARD. Mr. President, I would like to respond to this concern about drug companies investing relatively little and having huge returns. That doesn't apply to every drug.

Obviously, when you are developing a product for the market, there will be some that work out rather easily and the development costs may not be too much. But there are other drugs that require a substantial amount of work and analysis, and a considerable amount of thought has to go into the labeling. When those costs get high and when you hit those, the profit margin is not so large. I hate to see us pick out a few companies that may have had a windfall and then punish our children and say we are going to take away an incentive that has resulted in 80 percent of the children's drugs that have come to the market being approved and getting the proper licensing they require.

In my view, we pick out a few outrageous circumstances and then we try and take away an incentive that has been working so well for us.

My point, again, is why mess with that incentive when it is working so very well? As I had indicated here on the charts, we had such tremendous results in getting children's pediatric drugs to the market. This allows the pediatrician more choice in selecting therapies for their patients. It means better medicine. I also believe that the more products you have on the market, the more competition you have, and the more competition you have, that then holds down the price of drugs. What we need to do is rely on the markets to control the price of drugs, to control supply. I hate to see the Government or this Congress try to apply any kind of artificial parameters that somehow or other would mean we would have fewer drugs for the treatment of our kids and their ailments.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I rise today in support of this amendment by Senator ALLARD which would strike a cap on pediatric research incentives for blockbuster drugs with more than $1 billion in annual sales. That sounds like a lot. We are going to quibble here about whether they get 3 months of additional time or 6 months of additional time. They have had 6 months of additional time.

Incidentally, this is one time per drug. This is not every time they can come up with a child's use they can extend another 3 months or 6 months; this is one time on any drug, they can get an extension of 6 months.

Now we are going to decide that a company that comes up with a really great drug is only going to get 3 months versus 6 months because they make $1 billion in annual sales? Three months' worth would be $250 million in annual sales, and that sounds like a lot, but when you figure out what is profit out of that, it is a much smaller number.

I congratulate Senator DODD for originally coming up with this incentive. He came up with the idea for 6 months, and it worked. You have seen the chart that shows how dramatically there was an increase in the number of drugs that were studied for kids and how proper doses were derived for kids. The Allard amendment ensures that pediatric studies that are essential to our children's health and well-being will continue to take place, that they

will continue the same as they have with the same incentives and the same requirements. Under current law, in exchange for performing a pediatric study, a manufacturer can receive an additional 6 months of market exclusivity, one time per drug. This is a powerful incentive to ensure pediatric studies are completed. The substitute amendment we are debating today limits this exclusivity to just 3 months, and I am concerned that this will reduce or limit the number of pediatric studies. Senator ALLARD's amendment would revert back to current law. If we support and pass the amendment of Senator ALLARD, we go to current law, so manufacturers can receive the additional 6 months of market exclusivity.

Before incentives, there were very few pediatric studies. In the 7 years before Congress authorized incentives, only 11 pediatric studies were completed; 7 years, 11 studies—embarrassing. But at least 132 pediatric studies were completed, and more are ongoing. The current incentive system works.

This is not an abstract policy issue. Pediatric drug studies can mean the difference between life and death for our children. For example, initial research indicates that Viagra, which is a blockbuster drug, can work miracles for children with pulmonary fibrosis, a rare and potentially fatal lung disorder. Viagra seems to relax and expand blood vessels in afflicted children's lungs. Incentives spurred Pfizer to perform studies that are now underway and could save approximately 28,000 children who might otherwise die or suffer greatly. Without powerful incentives, such studies might not get done.

The Democratic witnesses at the HELP Committee's—the Health, Education, Labor, and Pension Committee—recent hearing agreed that caps are a risky experiment. The number—zero incentives, 11 studies; strong incentives, 132 studies—that speaks for itself. Reducing incentives will certainly reduce the number of pediatric studies. We should not undercut a system that is proven to help kids and then say we are improving the program. I don't think so.

I strongly agree we need to do everything we can to make health care more affordable and accessible, but harming a worthwhile program that saves kids' lives is the wrong way to do it. It is wrong to play the politics of drug pricing at the expense of our kids. We should protect these incentives which are proven to work.

Again, I congratulate Senator DODD for coming up with the idea of providing these incentives. I wish to note for the record it was at 6 months that we provided that. I ask that you support the Allard amendment.

I yield the floor.

The PRESIDING OFFICER (Mr. BROWN). The senior Senator from Connecticut is recognized.

Mr. DODD. Mr. President, let me first begin by thanking Senator KENNEDY and Senator ENZI for including the Best Pharmaceuticals for Children Act and the Pediatric Medical Device Safety and Improvement Act in the bill before us. I congratulate them, particularly Senator KENNEDY for his efforts of putting all this together, this major legislation which is going to be so important for the health and well-being of all our citizenry. I am very grateful to him, and to Senator ENZI as well, for leading the minority on this issue and making it possible for us to be here today to discuss these issues.

My friend from Colorado and I worked together on this issue. I appreciate the comments about the effort we made over the past decade or more to try to do what this bill was designed to do and has done, and that is to increase the clinical trials and testing of products used in our younger Americans—children.

In too many cases, prescription drugs were being tested for adults, and there was an assumption that a smaller dosage of that product would be all that was necessary to take care of children. Obviously, that was not the case, as we heard in significant testimony over the years.

Countless hours have gone into the work on this legislation. The Presiding Officer has been a tremendous help. I thank him for his efforts, along with others on this committee helping us put this together.

It must be an Ohio tradition. As he has heard me say on occasion, Senator BROWN has been tremendously supportive, working on this issue. He was active on the issue when he served in the other body, and he brought his talents and knowledge to the issue when he arrived here recently. His predecessor, Senator DeWine, was my cosponsor on this bill for a decade, on a bipartisan basis putting the legislation together that has produced the results which have been identified by Senator ALLARD and Senator ENZI already this morning.

We find ourselves here having worked very carefully together on a bipartisan basis for more than a decade to craft legislation. None of us are claiming perfection here. The idea was to try to induce the industry to step forward and do something they had not done before—to test their products in children. We were not certain when we started out how this would actually work. Ten years ago, we saw a situation where the majority of drugs being used in children were not being tested for their use.

Children are not simply little adults. The results of drug studies conducted under the Best Pharmaceuticals for Children Act have shown they should not be treated as such. The initiative contained in the bill before us on pediatric medical devices is a similar effort to ensure children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance.

Senator DeWine, as I mentioned, and I authored this bill more than a decade ago, at a time when only 11 drugs on the market that were being used for children had actually been tested and studied for that use. Prior to the enactment of this legislation a decade ago, pediatricians were essentially flying blind because they lacked information regarding the safety and effectiveness of drugs they were prescribing. It was often the children who suffered the most.

What we have learned over this past decade after 10 years of experience is that children have been exposed to ineffective drugs, ineffective dosing, overdosing, or drug side effects that were previously unknown. In 10 years, nearly 800 studies involving more than 45,000 children in clinical trials have been completed as a result of this legislation. Useful new pediatric information is now part of product labeling for more than 119 drugs.

In sum, there has been a 20-fold increase in drugs studied in infants, children, and adolescents as a result of the legislation I authored 10 years ago. Children with a wide range of diseases such as HIV/AIDS, cancer, allergies, asthma, neurological and psychological disorders, and obesity can now lead healthier and more productive lives as a result of new information about the safety and efficacy of drugs they use to treat and manage their diseases when previously there was none. This successful program for children will expire on the 30th of September unless we reauthorize it.

I have spent months crafting a proposal to reauthorize this legislation, which is now reflected in the underlying bill. It had been my hope that this initiative would continue in that bipartisan tradition that began more than a decade ago. Fashioning legislation when there are 100 of us here, trying to come up with ideas, and yet balance disparate views and opinions. There are some, frankly, who would have no periods of exclusivity and believe the industry ought to be doing this as a matter of obligation to one out of four Americans. You have heard from others who think we ought to provide extended periods of exclusivity, longer than 6 months. It is not easy to fashion these compromises here, where you can put something together that does what we want to do, all the while ensuring that the program can continue to generate more benefits than were originally contemplated. There has to be some limitation in terms of how we deal with all this.

I thank Senators KENNEDY, HARKIN, BINGAMAN, MURRAY, REED, CLINTON, and BROWN, who all cosponsored the legislation I introduced which, as I previously mentioned, has been incorporated on this bill.

Mr. President, I will ask unanimous consent that these letters be printed in the RECORD so my colleagues will know the bill we are considering is not something we threw together haphazardly. This was major, extensive work with major organizations in this country

that spend every waking hour working on children's diseases and issues that affect their health. I am grateful to the AIDS Alliance for Children, Youth & Families; the American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics; the American Brain Coalition; American Pediatric Society; the American Psychiatric Association; the American Thoracic Society; the Arthritis Foundation; the Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; Elizabeth Glaser Pediatric AIDS Foundation; National Association of Children's Hospitals; National Organization for Rare Disorders; Society for Pediatric Research—the list goes on.

I ask unanimous consent to have printed in the RECORD two letters from this myriad of organizations which every day are involved with children's health and are strong advocates of what we are doing here and respectfully disagree with the amendment offered by Senator ALLARD today.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

APRIL 17, 2007.

Hon. EDWARD KENNEDY,
Hon. CHRISTOPHER J. DODD,
Hon. MICHAEL B. ENZI,
Hon. HILLARY RODHAM CLINTON,
U.S. Senate,
Washington, DC.

DEAR SENATORS KENNEDY, ENZI, DODD AND CLINTON: As organizations working to ensure better health care for the nation's children, we write to thank you for your longstanding commitment to children's health and to express our support for legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) and to improve children's access to safe medical devices. We are very pleased that BPCA and PREA reauthorization language and S. 830, the Pediatric Medical Device Safety and Improvement Act, have been included in the Chairman's mark of S. 1082, the ''Food and Drug Administration Revitalization Act,'' for consideration by the Senate Health, Education, Labor and Pensions Committee tomorrow.

Over the past decade, Congress has enacted bipartisan legislation that has dramatically increased the number of drugs tested and labeled for children. The results from BPCA are extraordinary—over 336 requests have been generated for over 780 pediatric studies, resulting in over 115 new drug labels for children. Sen. Dodd's BPCA reauthorization language strengthens this very successful existing program in several important ways, including ensuring prompt label changes, requiring that all study protocols and results be made public, improving adverse events reporting for children, and identifying and addressing important gaps in treatments for children's diseases. In addition, the BPCA language includes a reasoned approach to address the small percentage of drugs for which the exclusivity provision has far exceeded the incentive it was intended to provide pharmaceutical companies.

S. 993, the Pediatric Research Improvement Act (PRIA), introduced by Sen. Clinton and included in the Chairman's mark, reauthorizes the Pediatric Research Equity Act of 2003 (PREA), which requires drug manufacturers to test their products for use in children. This law ensures that children are not a therapeutic afterthought and has generated impressive and invaluable safety and dosing information for children. Since the 2003 passage of PREA, 55 drugs have new or improved pediatric labeling. These drugs range from treatment of ear infections to the prevention of rejection of organ transplants. S. 993 places children on equal therapeutic footing with adults by creating the presumption that medicines coming onto the market for illnesses and conditions that occur in children will be labeled for pediatric use and be available in formulations (e.g., liquids, chewable tablets) that children can take.

The Pediatric Medical Device Safety and Improvement Act of 2007 provides a comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance. Like drugs, where for too long children were treated like small adults, many essential medical devices used extensively by pediatricians are not designed or sized for children. According to pediatricians, the development of new medical devices suitable for children's smaller and growing bodies can lag 5–10 years behind those for adults. S. 830 improves incentives for devices for small markets—while still preserving the ability to ensure the safety of new products once on the market. It provides assistance to innovators, streamlines regulatory processes, and elevates pediatric device issues at the Food and Drug Administration (FDA) and the National Institutes of Health.

Despite support for the Chairman's mark, we are disappointed that a key provision to make PRIA permanent has been omitted. As this legislation moves to the floor of the Senate, we urge you to restore the permanent authority of the FDA to ensure that children have properly studied medications as a matter of fact, not chance.

We are grateful for your longstanding leadership and commitment to improving the health of our nation's children and look forward to working with you toward swift Committee action and passage of these pediatric therapeutic bills by the full Senate.

Sincerely,

American Academy of Pediatrics; Elizabeth Glaser Pediatric AIDS Foundation; AIDS Alliance for Children, Youth & Families; American Academy of Child and Adolescent Psychiatry; American Brain Coalition; American Pediatric Society; American Psychiatric Association; American Thoracic Society; Arthritis Foundation; Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; National Association of Children's Hospitals (N.A.C.H.); National Organization for Rare Disorders; National Research Center for Women and Families; Society for Pediatric Research.

MAY 1, 2007.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: As organizations working to ensure better health care for the nation's children, we write to express our support for your legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA), which has been included in S. 1082, the ''Food and Drug Administration Revitalization Act.'' Since its original enactment in 1997, this legislation has directly resulted in an extraordinary increase in the number of drugs tested and labeled for children. In the past ten years, BPCA has prompted over 780 pediatric studies and yielded 115 new drug labels for children, fundamentally changing the practice of pediatric medicine and the quality of health care for our nation's children.

Since the inception of BPCA, Congress has recognized the need to ensure that it strikes the appropriate balance between cost to consumers and benefits to children. This year we have the data to show that we can adjust the exclusivity provision without losing pediatric studies. In February, the Journal of the American Medical Association (JAMA) published a study of the profits drug manufacturers received from the additional 6 months of pediatric exclusivity. The study found that ''the Pediatric Exclusivity Program overcompensates blockbuster products for performing clinical trials in children.''

The approach taken by your BPCA reauthorization legislation appropriately addresses the small number of products for which the benefit of additional exclusivity has far exceeded the incentive it was intended to provide. By limiting exclusivity only for those products with sales over $1 billion, your proposal can address concerns about excessive profits without jeopardizing the extraordinary benefits of BPCA for children's health. The adjustment will significantly reduce the overall cost of pediatric exclusivity to consumers. We therefore oppose Senator Allard's amendment to strike this reasonable exclusivity adjustment from S. 1082.

We are grateful for your leadership and commitment to improving the health of our nation's children and look forward to swift passage of BPCA by the full Senate.

Sincerely,

AIDS Alliance for Children, Youth & Families; American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics; American Brain Coalition; American Pediatric Society; American Psychiatric Association; American Thoracic Society; Arthritis Foundation; Association of Medical School Pediatric Department Chairs; Children's Cause for Cancer Advocacy; Elizabeth Glaser Pediatric AIDS Foundation; National Association of Children's Hospitals (N.A.C.H.); National Organization for Rare Disorders; Society for Pediatric Research.

Mr. DODD. To anyone offering to flyspeck this proposal and offer variations to it, I would say that months and months have gone into this legislation which we think has had the dual effect of ensuring that the ramifications of expanding the length of exclusivity, as some have proposed, have been carefully considered along with proposals to limit the length of exclusivity to 3 months for all drugs, as others have proposed. The bill before us balances many viewpoints on this program and is a proposal that 15 major organizations involved with the effort strongly support.

Throughout the 10-year history of the Best Pharmaceuticals for Children Act, Congress has recognized the need to ensure it strikes the appropriate balance between the cost to consumers and benefits to children. By instituting a 5-year sunset in both the original legislation in 1997 and the first reauthorization in 2002, Congress was acknowledging the ongoing need to evaluate the cost of the incentive under this act to consumers in relation to the benefit of having medications properly studied and labeled for children.

The 6-month incentive of exclusivity has been very successful in generating pediatric studies. Yet after 10 years,

experience and data have shown us that for a small number of drugs, pediatric exclusivity has far exceeded the carrot that was designed to encourage people to move forward.

In February of this year, the Journal of the American Medical Association published a study of the profits drug manufacturers received from the additional 6 months of pediatric exclusivity.

The study found that most of the drugs studied under the Best Pharmaceuticals for Children Act in recent years received relatively modest returns. In fact, data shows that many drugs came close to breaking even with respect to financial returns on investment for conducting pediatric trials. In one place they may have had a negative return.

However, the study also found, and I quote them here, that ''the pediatric exclusivity program overcompensates blockbuster products from performing clinical trials in children.''

S. 1082 contains a very reasonable, workable mechanism to address cost concerns. By adjusting exclusivity from 6 months to 3 months only for those products with U.S. sales over $1 billion, I think S. 1082 can address consumer concerns about excessive profits without jeopardizing the extraordinary benefits of this legislation.

I don't think it is too much to ask. That is why we have the sunset provisions in this program, to be able to go back and analyze how this is working every 5 years. So for those products in excess of a $1 billion, we shorten exclusivity. I am satisfied.

Pfizer, a leading drug company in this country, supports this proposal. The producer of the largest blockbuster drug in the world says this is a good compromise. Why are my colleagues having a hard time? If a major drug company who has benefitted under this exclusivity and manufactured blockbuster drugs says this bill is a sound compromise, what is the problem my colleagues have with this proposal?

If Pfizer, a company that has benefitted from this program says this balance is a healthy one, why can't my colleagues be happy with it?

This bill is a good bill. It has done a good job for people. But let's remind ourselves that we also have a responsibility to consumers. And when consumers find themselves in a situation where they can't afford lifesaving medicines, then it is time for us to strike a balance. This bill has a sunset provision in it. I am for the sunset provision. I am for it because we need to come back again in 5 years and assess where we are on this issue rather than make a determination that in perpetuity this is a program and a balance that makes sense forever.

According to the Congressional Budget Office, eliminating the exclusivity adjustment, as the amendment offered by my colleague from Colorado would do, would increase the cost of exclusivity to the Federal Government by $50 million over 10 years. So in addition to the consumers, taxpayers are going to be asked to pay an additional $50 million under the Allard amendment.

Again, if we have drug companies saying they think this proposal is a good balance, why are we adding a $50 million pricetag to the taxpayers with the Allard amendment, not to mention the cost of these drugs increasing as a result of extending exclusivity from 3 months to 6 months for products with sales in excess of $1 billion?

As I said, this is something I have worked on for a long time in a bipartisan fashion: to strike a balance as we've tried to do for 10 years between benefits to children and cost to consumers. To now say all of us who have worked on this program are wrong, all of the organizations involved with children's health are wrong, and drug companies that have benefitted from this program are wrong—but we know best. We know best. We think those billion-dollar products deserve to be protected. We think the taxpayers should foot the $50 million bill and the cost of these drugs are irrelevant in this debate. Well, they are not irrelevant.

We may do great damage to something we are trying to achieve after a decade of hard work on a bipartisan basis to put this together. I say respectfully to my friend from Colorado and the Senator from Wyoming, we have worked hard to strike these balances. It is not easy. These are complicated issues. It requires cooperation on both sides of the aisle to get the job done. That is what I have done for a decade with Members of that side of the aisle to see to it that we have a good, strong bill. The result is a program which has gone far beyond what we anticipated might happen.

The slight adjustment we have made after analyzing this bill after 10 years is little to ask. If one of the largest beneficiaries of the program is satisfied, and if the organizations who support this program believe it is all right, why are we adding a $50 million pricetag and asking consumers to pay more?

I urge my colleagues to reject the Allard amendment when the vote occurs. I thank Senator KENNEDY and others who have worked so hard to make this possible. This is a very important piece of legislation, and one that can do an awful lot of good. The amendment offered by my colleague from Colorado puts that at risk. Our children in this country deserve better than what he is offering, which is to try to break up the delicate balance I have tried to put together for a decade.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, I thank my dear colleague from Tennessee for allowing me to go first, and also my two colleagues on the Democratic side, Senators CARPER and STABENOW.

I ask unanimous consent that Senator ALEXANDER be permitted to go next and then Senator CARPER and then Senator STABENOW.

The PRESIDING OFFICER. Is there objection?

Mr. KENNEDY. Reserving the right to object, I think it would be useful if we rotate it back and forth.

Mr. HATCH. I think we have an agreement among the four of us.

Mr. KENNEDY. If the Senator from Delaware is satisfied, that is fine with me.

Mr. ENZI. One of the things we are trying to do is keep the debate on the children's amendment so we can get a conclusion to the children's amendment before time deadlines come up. So if those who wanted to speak on other issues can reserve their time until later, that would be very helpful.

Mr. HATCH. I would add to that request the Senator from Oklahoma after Senator STABENOW.

Mr. KENNEDY. We still have the Pastore rules in effect, which means the debate on the first 2 hours is supposed to be on matters which are subject to it. I mean it is not generally enforced, but Senator ENZI and I are trying to move forward.

The PRESIDING OFFICER. Is there objection to the unanimous consent request from the Senator from Utah?

Without objection, it is so ordered. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, I thank my colleagues, including the two managers of the bill on both the Democratic and the Republican side.

I rise in support of the Allard amendment. I want to take a few minutes to talk about pediatric testing and research provisions included in this bill. I have strongly supported both the Best Pharmaceuticals for Children Act and the Pediatric Research Improvement Act.

As my colleagues know, current law provides 6 months of exclusivity for drugs that do research and development in the area of pediatric use. I am very interested in keeping it that way. That has proven very efficacious in the Hatch-Waxman bill. It keeps companies involved in developing great drugs for children in this area. So it is a very important part of this.

I was deeply involved in those negotiations in 1997 with my former colleague, our former colleague, Senator Mike DeWine. I have supported these efforts from Ohio Senator Mike DeWine that brought additional pediatric testing of prescription drugs to our attention during consideration of the FDA Modernization Act of 1997. He fought long and hard to encourage drug companies to conduct clinical trials on pediatric uses of their drugs.

His efforts paid off and this program has been extremely successful. As a result, pediatric drugs are safer and more effective for children. The bill before us today reduces the 6-month exclusivity period for blockbuster drugs to 3 months.

I emphasize again this market exclusivity has provided the incentive needed to increase research and development for pediatric drugs. We used the

same type of an approach on the orphan drug bill many years ago. At that time there were only a few orphan drugs. Today there are over 300 being developed. It is the same principle here.

The Allard amendment restores current law and provides 6 months of exclusivity for all drugs. As I mentioned last night, my good friend and colleague from Connecticut, Senator CHRIS DODD, has also shown great leadership on this issue when FDAMA was being considered in 1997. He held a hearing on this issue earlier this year with his ranking Republican member, Senator LAMAR ALEXANDER, who has served long and well on this committee.

That hearing was very insightful, and I believe many of us are trying to do the right thing as we reauthorize both programs. I urge my colleagues not to lose sight of the purpose of these two programs as we make decisions on this part of the bill. We want good solid information about the safest way to prescribe drugs for children.

By giving companies market exclusivity to conduct clinical trials, we will know the safest dosage levels for children. So let's not lose sight of the original purpose of these programs: to help children have the safest dosages for prescriptions.

Now, it is no secret I support the Allard amendment. I would just like to add a few more facts. Nearly two-thirds of the drugs prescribed for children have not been studied and labeled for pediatric use. I know the importance of accurate clinical information about a drug's use in the pediatric population. This smaller body mass and higher metabolic rates of children mean they often respond differently to drug dosing than adults do.

A drug that is safe and effective in adults may not always be safe for children. The question is not whether we should study the safety of drugs for children but how we make that research happen.

In 1997, Congress considered this issue and created an incentives program for companies to study the use of their drugs in pediatric populations. The program offers an additional 6-month patent protection or exclusivity to drug manufacturers to help recoup the cost of investing in these critical pediatric studies. It is a win-win situation. Drug companies have the incentive to invest time and extra resources for a small share of the market, and, more importantly, children get the research they need.

The evidence is that the incentives for exclusivity should be maintained, not lowered. Despite the fact that the bill providing the incentive for pediatric studies was enacted a decade ago, nearly two-thirds of the drugs prescribed for children have not been studied and labeled for pediatric use.

We have had a great deal of study about the need for this incentive and how it should work.

The fact remains that there is a persistent public health need for accurate clinical information about how adult drugs will work in children.

Children are not adults, for reasons that the Senator from Oklahoma, Dr. COBURN, has well explained to this body.

Much of what our colleague from Connecticut, Senator DODD, has just said underscores the need for a continued, strong, exclusivity provision.

The statistics he cited about the success of this program are truly remarkable and a significant milestone in the history of public health.

The only place where there seems to be disagreement on Best Pharmaceuticals for Children Act is the exclusivity period for what some define as ''blockbuster drugs.'' I know the Senator may call the 6 months period ''gouging'' but that ''gouging'' may very well be the incentive that has led to the FDA receiving more than 400 proposed pediatric-study requests and receiving 144 completed studies.

Those who support the Senator's amendment—and I know it is well-intentioned—suggest that without the 6 months' incentive, the pediatric testing will still continue and will be robust. Who knows if this is true?

I wonder if we want to call their bluff and take away this powerful incentive? I don't think we can take that chance.

The PRESIDING OFFICER. The Senator from Tennessee is recognized.

Mr. ALEXANDER. Mr. President, first I would like to congratulate Senator DODD and others who over the past 10 years have developed this piece of legislation. It has been remarkably effective. I think it is important as we talk about this that we remind ourselves what we are saying. What we are saying is, we live in this country with all of these wonderful pharmaceutical drugs for adults, but in many cases, before this legislation had been enacted, doctors were flying blind. They were guessing about the effect of these drugs on children.

That sometimes had very unfortunate results. I know that in my home State of Tennessee a drug for whooping cough was given to a number of children. There had been a clinical trial for the effect it would have on adults but not on children. And the children were so seriously harmed by the drug that the Centers for Disease Control later found that the drug was the reason they needed stomach surgery.

So it is remarkable that 10 years ago Senator DODD and others—Senator DeWine, Senator HATCH, and many others who have been mentioned—came up with the idea that if we strike this balance that Senator DODD has referred to several times and give the companies that make the drugs a little more time, 6 months with their patent, that they in return would then conduct trials on these drugs on how they affect children.

No one knew at that time exactly what would happen. They were guessing. This is long before I came to the Senate. But they guessed well. As a result, as has been said, about one-third of the drugs that are given to children now have had testing and trials for use in children. Now doctors, when we bring our babies and grandbabies in, have a better idea of what they are doing. They are guessing less. It is better for the children.

In my family we have two new grandchildren under the age of 2. Senator DODD, being younger than I am, has two children who are young like that. Maybe he has heard what I have heard. My mother used to say to me when I would go to the babies and they were happy, she would say: ''Son, don't try to make a happy baby happier.''

In effect, what she was saying is, leave it alone if it is happy. Well, this is a happy piece of legislation for which Senator DODD and others should have a lot of credit. My suggestion would be let's not try to make a happy piece of legislation happier. It is happy because one-third of medicines are being studied, and doctors know more about what they are giving to their patients who are children.

What the Allard amendment would do is keep the law the way it is. It is the bill that is on the Senate floor that would change things.

I understand this is an estimate, but I listened to the testimony. The Senator from Connecticut suggested we are all racing here at the last minute and changing it. Wait a minute. We had a hearing on this some time ago. It was a terrific hearing. I was there. We heard various points of view, a lot of celebration about the effect of this act over the last 10 years. The only reason I was not a cosponsor of this legislation was because I wanted to hear the testimony about what the effect would be of changing this law that is a happy law that has worked so well for so long. As a result, it created the situation where a third of the children have drugs that doctors know more about.

After listening to all the testimony, if I were going to change the law, I would make the incentive 7 months or 8 months or 9 months. Why would I do that? The reason is, at the hearing it was said that while a third of the drugs that are administered to children have had been tested for use in children, probably we need two-thirds of the drugs that are ready for adults to have that sort of testing. In other words, we are about halfway where we want to go if we want to have drugs that are tested to see what their effect will be on children.

So my question was, if giving 6 months' incentive has gotten us halfway where we want to go, then maybe to get all the way where we want to go, we should go to a 7 months' or 8 months' incentive. But my feeling at the end of the hearing was, well, the existing law has worked well by providing an incentive of 6 months. Let's leave it like it is. The end result of the legislation that is on the floor is not to

leave it like it is but to change it, to reduce it from 6 months to 3 months, which is exactly backwards.

What the effect of this reduction will be is to reduce the opportunities for tests of drugs for children, which would fail to move us along toward the goal of having two-thirds of drugs studied for use in children.

I applaud Senator DODD. I give him great credit for this. When he retires from the Senate in another 30 years, this will be one great feather in his cap, as well as for Senator CLINTON and others who have worked on this. But I would go back to what my mother said: ''Don't try to make a happy baby happy.'' Let's not try to make a happy piece of legislation happy. Let's leave it the way it is. It has worked for 10 years. Let's let it work for another 5 years the way it is. Adopting the Allard amendment would keep it the way it is.

I have one suggestion for Senators KENNEDY and ENZI, if I may. Maybe they would want to consider it as part of the managers' amendment. We heard testimony at our hearing that perhaps our goal should be someday to get two-thirds or three-fourths of the drugs that are for adults studied for use in children. Today it is one-third. I think it would be useful for us at a future time to know exactly what our goal ought to be. Maybe it ought to be 90 percent. Maybe it ought to be 50 percent. But I wanted to suggest to the Senator from Massachusetts and the Senator from Connecticut that we might want to include in this legislation asking the FDA or the appropriate agency to study what percent of drugs approved for adults should also be tested for children, what is that proper goal, so that the next time this issue comes up we have some informed judgment about it. A quick review of the medical literature shows there hasn't been any such study. I could be corrected if there has been. If there hasn't been, I suggest we make that a part of the legislation. I make that simply by suggestion, not amendment. I intend to vote for the Allard amendment, and I have stated the reasons why. If we have a happy piece of legislation, let's keep it happy. That will do it.

I yield the floor.

The PRESIDING OFFICER. The Senator from Delaware.

AMENDMENT NO. 990

Mr. CARPER. Mr. President, I wish to change the subject for a moment, if I may. The overall subject is the same; that is, the legislation that is before us. I salute Senators KENNEDY and ENZI and their staffs for providing an excellent piece of legislation. It was not an easy thing to do on a difficult subject. I thank them for their efforts and for getting us to this point.

Yesterday evening, our colleagues and friends, Senators DORGAN and SNOWE, filed an amendment to S. 1082 that would allow for reimportation of prescription drugs from Canada and from certain other countries. In previous years, a number of us, including me, supported reimportation legislation, so long as the Secretary of Health and Human Services certifies that the reimportation of prescription drugs can be done both safely and cost-effectively.

Earlier this morning Senator COCHRAN filed a second-degree amendment to the Dorgan-Snowe legislation that seeks to require that certification in the context of this legislation that is before us today. Senator COCHRAN's amendment would require the Secretary of Health and Human Services to certify that the provisions within the Dorgan-Snowe reimportation program would pose no additional risk to the public's health and safety.

In addition, the Cochran amendment would require the Secretary of Health and Human Services to certify that this reimportation program would result in a significant reduction in the cost of prescription drugs to the American consumer. So there are two goals. These few lines that Senator COCHRAN just introduced were passed by unanimous consent 4 years ago in 2003. In 2002, this language passed the Senate by a vote of 99 to nothing. It is clear, at least to me, from these past votes that this is not the first time the Senate has taken up this issue and, again, with some consensus.

Since the last time reimportation was before this body, Senators DORGAN and SNOWE have worked hard to address many of the safety concerns folks had raised in previous iterations. I commend both of them and their staffs for working diligently to try to address a number of these concerns. I believe they have made significant progress. For instance, concerns were voiced earlier that the FDA would not have enough funds to operate a reimportation program. To provide the FDA with additional resources, the revised Dorgan-Snowe proposal would increase user fees paid by those drug wholesalers and pharmacies participating in the program from 1 percent to 2.5 percent of the total price of the drugs that are reimported. This moves us closer to ensuring that FDA will have the resources they need to operate this program effectively.

Senators DORGAN and SNOWE'S new legislation would also allow the FDA more time to phase in the number of drug exporters and importers that want to participate in the program. A slower phase-in would give the FDA more time to ensure that the importers and exporters are aboveboard and should help alleviate concerns that we would unknowingly allow unscrupulous vendors into this reimportation program.

Although Senators DORGAN and SNOWE address a number of the drug safety concerns, I believe a couple of possible shortfalls remain, especially when it comes to stopping the proliferation of counterfeit, adulterated drugs. Specifically, this legislation relies on what are called paper pedigrees to show a drug's chain of custody, but there is no guarantee that these paper pedigrees could not be forged to hide possible counterfeiting, possibly leaving American consumers with a less safe drug supply. Moreover, this bill relies on what some believe are unproven and untested anticounterfeiting technologies to guarantee drug safety. While I give credit to my friends for trying hard to build safety into the proposal, it is not yet clear that anticounterfeit technologies, which the proposal relies so heavily upon, is yet at the point of being both widely available and, more importantly, cost effective.

In addition, it is unclear to me if this reimportation program would give the FDA the authority to conduct inspections of foreign manufacturing plants. It is unclear to me whether the countries permitted under this bill to export drugs into the United States have the same kind of safety and quality control standards that we enjoy at home.

In the end, drug reimportation will only work if we are able to ensure that the drugs we import are as safe as those manufactured and sold in the United States. If the Secretary of Health and Human Services, the person who directly overseas the FDA to ensure the public's health and safety, is not prepared to certify that the importation is safe, then that gives me pause, and I believe it should give us pause. We don't have a reimportation program operating right now, but the incidence of drug counterfeiting and adulterated drugs still exists. In the last few years, prescription drugs that contained bogus or dangerous ingredients as well as actual drugs that were deceptively labeled to hide their origin have made their way into the United States. For example, 4 years ago, counterfeits of the cholesterol drug Lipitor were found in the United States and made their way to a number of American consumers. Recently, FDA warned consumers about counterfeit drugs from multiple Internet sellers.

Many would argue that the FDA already has its hands full. If that is true, how do we in good faith add another layer of complexity such as reimportation to an already overburdened and underresourced system without also demanding that the Secretary of Health and Human Services certify that reimported drugs are safe for American consumption.

Similar to most of my colleagues, I am not opposed to reimportation, but I do firmly believe that despite the very real progress that has been made with respect to the earlier Dorgan-Snowe proposal, some uncertainties remain in the revised legislation they offered yesterday. Because of those remaining concerns, I support the Cochran amendment and ask my colleagues to do the same.

Similar to some of my colleagues, I have held in my hands medicines that appear to be the same as the prescription medicines manufactured in this

country. They were the same size, same shape, same color. They have the same markings. The wrapping and the materials they come in are the same. They appear to be, for all intents and purposes, the same legitimate prescription medicines. They were not. In some cases, they contained materials that were unsafe, and in other cases they contained materials that were not helpful to the person suffering from a particular malady. I would like to say that those concerns for that kind of behavior have gone away. They haven't. The profit motives for those who would like to sell bogus drugs, counterfeit drugs, the economic attraction of doing that is enormous. As a result, I think we need to proceed with caution.

I again commend Senators DORGAN and SNOWE. They are trying hard. Their staffs are trying hard to get us to the point where the Secretary of Health and Human Services can actually certify that we can reimport these drugs in a way that is safe and cost effective. We will be voting later today to determine whether we have gotten that far. The Cochran amendment made sense before, and I think it still makes sense.

I yield the floor.

The PRESIDING OFFICER (Mr. CASEY). The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, for the benefit of the Members and the greatest convenience, we will vote on the Allard amendment at 12:25. What I would like to do is propose a consent agreement that we vote at that time. I know the Senator from Oklahoma and the Senator from Michigan want to talk. We have 35 or 40 minutes. Probably Senator ALLARD and Senator DODD would want to make a comment before we get to the vote.

I ask unanimous consent that at 12:25 the Senate vote in relation to the Allard amendment 982 and that the time until then be for debate with respect to the amendment, with the 40 minutes divided as 20 minutes being divided equally between Senator ALLARD and Senator DODD and 20 minutes between the Senator from Michigan and the Senator from Oklahoma; furthermore, that no amendments be in order to the amendment prior to the vote.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senator from Michigan.

AMENDMENT NO. 1011

Ms. STABENOW. Mr. President, first, I ask unanimous consent that the pending amendment be temporarily set aside and call up amendment No. 1011 for the purposes of offering the amendment.

The PRESIDING OFFICER. Without objection, the pending amendment is set aside. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Michigan [Ms. STABENOW], for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL, proposes an amendment numbered 1011.

Ms. STABENOW. Mr. President, I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To insert provisions related to citizens petitions)

At the appropriate place, insert the following:

SEC. ___. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(r) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION.—The receipt of a petition is not just cause to delay consideration of an application submitted under subsection (b)(2) or (j) and consideration of a petition described in clause (i) shall be separate and apart from the review of an application submitted under either such subsection.

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 30 days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; and (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents. I further certify that the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.''.

Ms. STABENOW. First, Mr. President, I thank Senator KENNEDY for his incredible leadership and work on this very important legislation, and Senator ENZI, as well, for his leadership and work and partnership with Senator KENNEDY on this legislation. I also thank Senator DODD for his years of advocacy for children. I join with him in opposing the Allard amendment, and believe Senator DODD has given us the first step as to where we need to go in terms of more medicines being available for children. I thank him for all of his leadership.

Mr. President, I today am offering an amendment—a bipartisan amendment, with Senator THUNE, as well as Senator LOTT and Senator BROWN; we also have Senator KOHL joining us—to close a loophole that the brandname pharmaceutical companies are using to prevent competition by delaying the entry of generic drugs.

Our amendment is based on the citizen petition provision that is included in a bill Senator LOTT and I introduced last session and again this session, but it has been greatly improved by contributions from Senator BROWN. I particularly thank him for his hard work and contributions to this amendment.

The citizen petition process is intended to allow citizens to raise legitimate issues regarding drug products, and it is very important we have that. However, the brandname pharmaceutical companies have increasingly used citizen petitions to delay access to safe, effective, and affordable generic drugs.

Simply put, citizen petitions have become PhRMA petitions to block consumers from having access to affordable medicines, unfortunately. The cost to employers, consumers, health insurance plans, and Government health plans, as a result of delayed entry of generics, amounts to hundreds of millions of dollars—and in some cases billions of dollars.

For that reason, our amendment has the support of a very broad range of consumer groups, business groups, labor, pharmacy, and other organizations, including the AARP, the chain drugstores, General Motors, Ford, DaimlerChrysler, the AFL–CIO, the Alliance for Retired Americans, CalPERS, the National Committee to Preserve Social Security and Medicare, Families USA, the Pharmaceutical Care Management Association, the UAW, and the Coalition for a Competitive Pharmaceutical Market, which is a broad coalition of our employers and insurers across the country.

What would our amendment do? Our amendment would, first, preserve the right to file citizen petitions and raise legitimate safety issues. This is very important. We do nothing to take away the citizen petition. It would reduce the filings, though, of frivolous citizen petitions, and it would stop frivolous petitions from delaying generic entry—and thus costing businesses, consumers, and taxpayers—by allowing needed competition to bring down prices in the pharmaceutical market.

It would do so by, first, requiring the generic approval process to move forward while a petition is considered, unless the petition has raised legitimate public health concerns about the drug.

Second, it would require that final action on a petition be taken within 6 months of the petition being received.

Third, it would require petitions to be signed and include a verification that the petitioner has taken reasonable steps to ensure all relevant information is included in the petition and whether any payments have been made in exchange for filing the petition. This is very important.

And, fourth, it would ensure transparency surrounding FDA's decisions on whether to delay generic drugs on the basis of a citizen petition.

Our amendment improves upon the language in the Stabenow-Lott bill in that it sets timelines for FDA to evaluate petitions and absolutely ensures that if it is a legitimate public safety issue, then medicines will not be approved unless and until the safety issues are resolved.

Why do we need this amendment? Any person or organization can file a citizen petition with the FDA raising concern. We certainly want people to be able to do that. However, the process right now is being used in ways that are unintended.

The Medicare Modernization Act closed a lot of loopholes that the brandname companies were using to delay generics from going into the marketplace. So, unfortunately, they have looked to another tool. They are now using these frivolous citizen petitions.

Between passage of the Medicare Modernization Act and April 30, 2006, brandname companies filed 45 citizen petitions requesting that the FDA delay approval of a competing generic drug. Of the 45 petitions, the FDA has ruled on 25 of them. Of the 25 petitions, 92 percent of them were denied.

The brandname companies often file these petitions right on the eve of the generic drug being approved, making it very clear that delay is the goal. These are ''11th hour'' petitions, as they have been called, and 12 of those ''11th hour'' petitions—12 of them—were denied in whole and 1 in part by the FDA.

What do the petitions ask for? Do they raise new and important issues? Unfortunately, the answer is no. Although the petitions are filed before or after a generic drug has received tentative approval from the FDA, they commonly simply request additional studies or additional data, based on mere speculation by the brand companies.

The FDA typically will not approve a generic drug until all the underlying issues of a citizen petition have been addressed. As a result, although the FDA regulators provide that citizen petitions should be addressed within 6 months—and that is what our amendment says—the average review time is 10 months. And 10 months means lots of lost dollars. It leaves consumers paying more, businesses paying more, and insurers paying more.

The fact is the vast majority of petitions filed by brand companies have nothing to do with science and everything to do with delaying generic drugs, stopping the competition. Consumers lose as a result of that.

In December 2005, Merrill Lynch released a report analyzing brand company use of the FDA citizen petition processes. The analysis involved a review of citizen petitions filed by brand companies since 2001. They said there was a ''sharp uptick'' in the number of citizen petitions filed by brand companies in 2004 and 2005 and,

> In many instances, the filing of [these citizen petitions] by branded companies coincided with the expiration of a product's patent (or other marketing exclusivity) effectively delaying generic competition for months and sometimes years.

Why is this important? Well, I want to give you a few examples.

Flonase is a drug that is used to treat nasal symptoms and allergies. It is a very commonly used drug. In this case, the brand company filed multiple citizen petitions in an effort to delay the generic competition, a lower priced drug, from going on the market. All three citizen petitions were denied.

According to the FDA:

> [The brand company] has not articulated sound public policy grounds for supporting a stay. In addition, [the brand name company] has not demonstrated that the delay resulting from the stay is not outweighed by public health and other public interests.

In other words, no sound public policy, but, unfortunately, the delay took months to resolve.

The following quote from Gary Buehler, Director of the Office of Generic Drugs at FDA, was reported in

the New York Times on February 23, 2006:

The agency was required to consider the petitions and to write responses. That took time and delayed the approval [process].

So what happened? Even though all of these petitions were denied by the FDA, it took so much time, and generic entry was delayed by 656 days, and the brand company was able to get $1.65 billion more in sales.

We see with all of these drugs shown on this chart delays that have, in fact, allowed the brandname company to be able to continue sales. Unfortunately, these higher costs are paid by our seniors, consumers, and businesses that offer medication, as well as by insurers themselves.

We have not only large delays, but even in the case of 5 days, $17 million more in sales. So there is great incentive to use delaying tactics in order to be able to continue this process.

Mr. President, I see my time is up. Let me say this amendment was carefully constructed to allow citizen petitions to continue. The overwhelming evidence from the Federal Trade Commission, the Office of Inspector General, as well as the FDA, and others—the overwhelming evidence is we are seeing this as a new loophole that is being used to delay effective competition and lower cost medicine from going into the marketplace. We can fix that and keep the citizen petition for legitimate issues. We certainly want that. We certainly are concerned about safety, as is the FDA. But it is time to close this loophole.

I thank my colleagues who are cosponsoring this amendment and urge support for the amendment.

The PRESIDING OFFICER. The Senator from Oklahoma.

AMENDMENT NO. 982

Mr. COBURN. Mr. President, I rise to speak for a minute in support of Senator Allard's amendment. I also want to recognize Senator DODD's work, and I believe he truly cares about us getting pharmaceuticals to children. But I think the bill as written today has some very great risks for our children.

I practice medicine. I can remember 25 years ago, for so many of the drugs, we did not know what we were doing as they related to children. We had sometimes great outcomes and sometimes poor outcomes as to the availability and knowledge of pharmaceuticals for children.

We have a system that started 10 years ago that has been highly successful. Mr. President, 144 drugs have now been studied in kids. We know what we are doing with 144 drugs. With 25 of those drugs, we now know not to use them for children.

How did we get there? We created an incentive that said: We will give you a 6-month patent extension if you will study pediatric indications and do a study on pediatric patients for this drug. It worked. As a matter of fact, it worked great.

Now, I am having trouble understanding, as a physician, the therapy Senator DODD wants to put on this. He is back to practicing medicine the way we did pediatrics 25 years ago with his amendment. I certainly hope he is right if he wins because there are going to be a lot of children in trouble if he is not.

What his amendment actually says is, if you made $1 billion off a drug, you only get a 3-month extension. I can see how we could look and say they are making too much money. But only 1 out of every 10 drugs we studied in pediatrics was a blockbuster drug. So what is happening with these high-profile drugs they are making a lot of money off of is they are the things that are funding the other 130 studies of drugs that are not blockbusters, that are not profitable.

So what Senator DODD has put in this bill—and I know it is well-meaning—is to limit that profitability, hoping drugs will become more reasonable, and gambling—a very risky gamble—that the research on pediatric drugs will continue with that 3-month extension.

He may be right. But as someone who cares for kids in my own practice, I am not willing to take that gamble. I am not willing to say: What if he is wrong? What if the studies go from 144 to 15?

Now that we are seeing all these new drugs coming out, we are not going to have a study for kids? We are going to take away opportunities for young children to have the benefits of a new drug because they are not studied? Or we are going to use the drugs anyhow, even though they are not indicated and we do not know what we are doing, in a hope—not in a knowledgeable, scientific way but in a hope we are doing some good?

We have a system that has worked very well. Senator DODD was supportive of that system. I do not know that he is right. He could be right. But the question will be: What if he is wrong? What if the next 100 drugs that come out for maladies that could have an application for children—especially some very small used drugs, specialty drugs for chemotherapy, and have a very low incidence of usage in kids—what if they are not available? What if they are not made available? How many children are not going to get that drug? Now the system is paying for 90 percent of the studies on drugs that aren't the blockbusters, and we are going to cut the incentive in half. It may work. I don't know where the knowledge is, the scientific inquiry, or the study that says that going from 6 months to 3 months is the right amount. What about 2 months? What about 1 month? What about 5 months? We don't know. So what are we going to do? We are now going to go back and practice on pediatric drug studies the way we used to practice on children. We are going to guess.

What the Allard amendment says is: We are not real happy there is this amount of tremendous profit, but we do understand that the profit off the blockbuster drugs is actually paying for 90 percent of the studies on nonblockbuster drugs for kids, that we are going to take away that incentive. It is really comforting as a physician to know now what I didn't know before in terms of giving a kid a medicine and knowing how it is going to be metabolized, knowing its half-life, knowing it is different in a child and being able to dose it correctly, and confidently saying to a parent: I have given you something that is going to fix your child, that is going to cure this illness, and I know you are not going to have a side effect from it.

What we have done has worked. Why would we mess with it unless we know? I have listened to this debate. I don't see anybody telling me how we know we are not going to disincentivize further drug studies. If somebody can show me that, then I will be happy to vote against the Allard amendment. But there is not anybody who can show me scientifically that we are going to have another 144 drugs studied if we cut this in half. Maybe we will, maybe we won't. I can't see into the future, but I am cautious enough to know I love the progress we have made.

If we change this, if we change it—and it sounds as if, from the debate here, the Allard amendment isn't going to be approved—we better darn sure know what we are doing, and we better darn sure say that taking money away from drug companies in terms of extending patents is not going to have a negative impact in terms of positive benefits.

I am not the greatest defender of the drug companies. I authored the first bill that was signed by President Clinton which allowed reimportation of drugs into this country. Why did I do it? I think we need to have a worldwide market on pharmaceuticals. We don't. We have a controlled market everywhere except in this country. The American taxpayers end up subsidizing the research and subsidizing the profits. But I also recognize that some of these drugs' profits are the very things that allow me to now give comfort to a mother and a father when they have a very sick child.

I hope Senator DODD has the wisdom to know that he has done it just right and that there is not going to be one cancer chemotherapeutic agent that wasn't studied in children because it is not a blockbuster drug, and now that we are going to cut it to 3 months, that there will still be an incentive to make sure that the next child with a sarcoma or the next child with an aplastic anemia or the next child with a leukemia that is resistant to bone marrow transplant or anything else is going to be able to have the medicine.

We are going to go back to the way we practiced medicine 10 or 12 years ago. We are not going to know, and we are going to shoot from the hip and pray and hope. What we have today is we don't have to pray and hope anymore. We now have the studies.

I don't know the answer to it, and I am not saying Senator DODD is wrong, but I think a legitimate question to ask is, What if he is wrong? What if he is wrong? How many children aren't going to have drugs? How many children are going to have a drug complication? How many children are going to have a drug interaction? How many children's lives aren't going to be saved because we decided the drug companies are making too much money and we are going to tell them how much they should make?

Mr. President, I yield the floor.

The PRESIDING OFFICER. Who yields time?

Mr. DODD. Mr. President, if I may, I would like to divide my 10 minutes, and I would like to spend a few minutes on another part of the bill, the Pediatric Medical Device Safety and Improvement Act.

I thank Senator KENNEDY and Senator ENZI for including this bill which I authored in the underlying legislation.

The pediatric medical devices provision of the underlying bill is not subject to an amendment, but I want my colleagues to know what we have done with this provision, which is a complementary piece of legislation dealing with a similar set of issues as under the Best Pharmaceuticals for Children Act. That is, ensuring that medical devices used in children are safe and designed specifically for children. One of the fundamental hurdles with respect to children is that the market for products designed for them is relatively small. However, I believe the proposals in the underlying bill will make a huge difference in the lives of children.

This initiative provides a very comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance.

Like drugs, where for too long children were treated like small adults and were just given reduced dosages, many essential medical devices used by pediatricians are not designed or sized for children, and that has been the case for many years. Pediatric providers have had to resort to jury-rigging or fashioning makeshift device solutions for pediatric use. When that is not an option, providers may be forced to use more invasive treatments or less effective therapies. This legislation addresses the need to promote pediatric device development by providing incentives to manufacturers while at the same time equipping the Food and Drug Administration with appropriate authority to monitor and ensure the postmarket safety of medical devices used significantly in children.

One such example which highlights the need for this legislation is a device known as the Vertical Expandable Prosthetic Titanium Rib, a device invented, developed, and brought to market by Dr. Robert Campbell, Professor of Orthopaedics at the University of Texas Health Science Center. Dr. Campbell appeared before the Health, Education, Labor and Pensions Committee in late March and testified about the arduous 14 years it took to bring the titanium rib to market. Dr. Robert Campbell made remarkable breakthroughs with this technology but the hurdles he faced were, at times, seemingly insurmountable.

I want to put up a photograph of a boy named Devin Alvarez, of Hialeah Gardens, Florida, which shows the remarkable difference this device has made for him. Devin was born with six ribs missing and a very small left lung and kidney. At birth, the doctors did not believe he was going to survive his first night. In May 2002, Devin underwent titanium rib implant surgery and the curve of his spine was reduced to 45 degrees. Devin stood straight for the first time in his life and, at present, Devin is a very typical 9-year-old boy who enjoys playing sports such as golf and baseball.

Again, remarkable ideas for pediatric medical devices happen regularly, but the incentives to transform ideas into new FDA-approved devices simply don't exist. So the motivation for the Best Pharmaceuticals for Children Act legislation 10 years ago dealing with pharmaceutical products for children is the same motivation behind this legislation—to encourage the medical device industry to develop and to engage in the kind of research to allow these technologies to emerge.

In describing the pediatric medical devices bill which is now included in this legislation, Dr. Campbell, who has been so instrumental in all of this, said:

> This bill represents an historic step forward for children's medical and surgical devices similar to those steps taken on drugs. It will help future medical inventors of pediatric devices to avoid my mistakes and my frustrations so that they can get their devices ''off the napkin,'' if you will, and into the pediatric patients who need them, in a safe and timely fashion.

I thank my colleagues from Massachusetts and Wyoming for working hard to make sure this will be a part of the underlying bill. I am grateful to them. It is my understanding that concerns have been raised by some in the medical device industry regarding a particular provision of the bill related to equipping the Food and Drug Administration with authority to ensure the safety of medical devices in children once they are already on the market.

The provisions in the bill mirror the recommendations made by the Institute of Medicine in its 2005 report on pediatric medical device safety. The Institute of Medicine found serious flaws in the current postmarket safety surveillance of these devices and the provisions in my bill correct those serious flaws. I am disheartened by those who would attempt to deprive children and physicians with information that pertains to device safety.

I think we have made some tremendous advances for children and their families in this legislation.

Mr. President, I ask unanimous consent that relevant material relating to the medical device provision of this legislation be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION,
Washington, DC, March 5, 2007.

Hon. CHRISTOPHER DODD,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DODD: On behalf of the Elizabeth Glaser Pediatric AIDS Foundation, I would like to thank you for your leadership in introducing the Pediatric Medical Device Safety and Improvement Act of 2007 and offer our strong support for this legislation, which will improve the health and well-being of children across the country.

This legislation will ensure that children enjoy the same protections as adults do when using necessary medical devices. Over the last few decades, countless innovative medical device products have been developed as a result of cutting-edge research and new technologies. As you know, children are being left out of the equation. Many challenges limit children's access to safe and effective medical devices, including differences in size, weight, metabolism rates, etc. With very few devices available for pediatric use, pediatric providers must resort to fashioning make-shift devices for their patients. Left with no alternative options, providers may be forced to use older or less optimal interventions, which can be less effective and could pose greater risk.

The Pediatric Medical Device Safety and Improvement Act of 2007 recognizes the urgency for greater development of medical devices created with children's special needs in mind. It provides a comprehensive approach to improving children's access to medical devices and includes provisions to assist innovators with technical and financial resources, streamline the regulatory processes, elevate pediatric device issues at the FDA and NIH, and improve incentives for devices for small pediatric populations—while still preserving the ability to ensure the safety of new products.

Thank you for your leadership and commitment to this issue. We look forward to working closely with you to ensure that children across the U.S. benefit from this important piece of legislation.

Sincerely,

PAMELA W. BARNES,
President and Chief Executive Officer.

THE SOCIETY FOR CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS,
Washington, DC, March 15, 2007.

Hon. CHRISTOPHER J. DODD,
Chair, Subcommittee on Education and Early Childhood Development, Senate Committee on Health, Education, Labor and Pensions, Washington, DC.

DEAR CHAIRMAN DODD: I am writing to express our support for passage of your Pediatric Medical Device Safety Act of 2007. We greatly appreciate your efforts to expand pediatric patients' access to safe medical devices. Your proposal will be an important step forward.

The Society for Cardiovascular Angiography and Interventions is a professional association representing over 3,700 invasive and interventional cardiologists. SCAI promotes excellence in cardiac catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient care.

Fortunately, cardiovascular disease is far less common in the pediatric population

than it is in the adult population. This good fortune does however frequently lead to unique challenges for the pediatric interventional cardiologist who treats these patients. Some of the challenges are clinical and we are more frequently solving those problems, saving children's lives and avoiding the trauma of surgery. Other challenges, and perhaps the most frustrating ones are related to obtaining the safe medical devices necessary to treat these patients. Devices that are available to our colleagues in Europe are not available in America. We support the FDA's efforts to ensure that only safe and effective medical devices are used on patients in our country, but when the entry barriers into the American markets are so high that manufacturers refuse to enter—some patients suffer and die needlessly. Required is an appropriate balance between the sometimes mutually exclusive goals of safety and availability.

We are especially pleased that your legislation will require the FDA to issue guidance to institutional review committees (IRCs) on how to appropriately consider the use of the humanitarian device exemption (HDE) at their institution. When HDE devices are not part of an ongoing trial, IRCs (which focus on reviewing the care of patients in trials) are sometimes confused.

We believe that giving the FDA explicit statutory authority to extrapolate from adult to pediatric patients in appropriate situations could help FDA officials expedite their review of some pediatric medical devices.

We applaud the provision that allows companies to make a profit on HDE devices designed for children. This change will encourage the development of more devices by providing an opportunity for profit and also by reducing concerns about audits, specifically those using different assumptions which could determine a profit was made when a manufacturer calculated their financial situation differently. We note that the 4,000 cap is arbitrary and far below the 200,000 patient limit that is placed on orphan drugs. We believe that more devices could be made available to pediatric patients and those with congenital heart disease if that cap is raised. We encourage you to consider such an increase either as a part of this legislation or broader FDA reform legislation.

We also understand that there are some concerns on the part of industry about the section 522 provisions of this proposal. As clinicians, we are not in a position to evaluate the precise impact of those provisions but we certainly hope those concerns can be resolved.

We look forward to working with you and your staff to support passage of this legislation and thank you once again for your efforts. Our Senior Director for Advocacy and Guidelines, Wayne Powell will be coordinating this effort for the Society and he may be reached at (202) 375–6341 or wpowell@scai.org.

Sincerely,

GREGORY J. DEHMER, M.D., FSCAI,
President.

FEBRUARY 28, 2007.

Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.

DEAR SENATOR DODD: On behalf of the 60,000 primary care pediatricians, pediatric medical subspecialists, and surgical specialists of the American Academy of Pediatrics who are committed to the attainment of optimal physical, mental and social health and well-being for all infants, children, adolescents, and young adults, we write today to express our gratitude and support for the ''Pediatric Medical Devices'' legislation. This legislation is an important step towards improving the process for the development of needed pediatric medical devices.

Children and adults often suffer from many of the same diseases and conditions, however their medical device needs vary considerably. Children are not just small adults and medical device technologies manufactured for adults often do not fit the needs of children. This problem forces pediatricians to ''jury-rig'' adult medical devices that are often too large, in order to make them fit smaller bodies. This practice, however, is not always effective and leaves children without optimal treatment. Additionally, children's device needs vary considerably due, not only to size, but also to different rates of growth, anatomy, physiological differences and physical activity levels.

This legislation offers incentives to device manufactures to create needed medical devices specifically designed to meet the needs of pediatric patients and it gives the FDA the authority to require post-market studies to ensure continued efficacy and safety of these devices. The need for pediatric medical devices to treat or diagnose diseases and conditions affecting children is clear; it is essential that medical devices be manufactured with children's needs in mind.

Thank you for your continued commitment to improving the health and well-being of children. We look forward to working with you as this important legislation moves through Congress.

Sincerely,

American Academy of Pediatrics.
American Pediatric Society.
Association of Medical School Pediatric Department Chairs.
Society for Pediatric Research.

STRYKER CORPORATION,
Washington, DC, March 6, 2007.

Senator CHRISTOPHER J. DODD,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DODD: On behalf of Stryker Corporation (''Stryker''), I am pleased to announce our support for your legislation to improve the availability and safety of pediatric medical devices—the Pediatric Medical Device Safety and Improvement Act of 2007. Like you and your colleagues, we want our children to have access to the fullest and best range of possible medical treatments, even if that means doing or inventing something new just for them.

We view this as our responsibility both as the leading manufacturer of orthopaedic oncology prostheses in the United States and as a global medical technology company with a significant presence in other medical specialties, including craniofacial deformities such as cleft lip and palate. We take pride in partnering with and sponsoring a range of medical organizations, including one which last year was able to provide free cleft lip surgeries to 8,531 children in 23 countries. The surgery took only about 45 minutes and cost $750 per child, but the corrective surgery changed, in a positive way, forevermore the lives of each and every child and the lives of their families, too.

We sincerely appreciate your leadership role on children's issues. We take very seriously not only our commitment to children with cancer and craniofacial deformities but also our responsibility to ensure that our devices are safe and effective for use in pediatric patients.

As you may know, there has been significant progress over the past two decades in the management of patients with musculoskeletal cancers that has improved both the survival rates and quality of life of afflicted individuals. Twenty years ago, the standard treatment for any primary malignant bone and soft tissue sarcomas of the extremity was amputation of the affected arm or leg. Since that time, Stryker is proud to have partnered with leading pediatric oncology surgeons to develop limb-sparing, surgical solutions, including the implantation of a growing prosthesis that can be elongated to account for children's growth.

As with cancer, the treatment of craniofacial deformities is an area in which Stryker has also significantly improved and broadened its range of available medical products and solutions. With continued innovation of new and improved craniomaxillofacial technologies, Stryker hopes to continue to transform the lives of children with craniofacial deformities, such as craniosynostis and cleft lip and palate.

It is our hope that your legislation will further spur the evolution of novel health care solutions for children. The bill's efforts to streamline approvals for devices with pediatric indications, improve incentives for the development of devices for small pediatric populations, and encourage the establishment of non-profit consortia for pediatric device development should be commended.

Stryker stands ready to assist you in your drive to stimulate the further development of child-centered medical technologies while closely monitoring the safety of such products after they have entered the market. Thank you again for your leadership on this important issue, and we look forward to working with you to advance your bill as medical device reauthorization legislation moves forward in the 110th Congress.

Sincerely,

ED ROZYNSKI,
Vice President,
Global Government Affairs.

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION,
Washington, DC, March 6, 2007.

Hon. CHRISTOPHER J. DODD,
Chair, Subcommittee on Education and Early Childhood Development, Senate Committee on Health, Education, Labor, & Pensions, Washington, DC.

DEAR CHAIRMAN DODD: On behalf of the Advanced Medical Technology Association (AdvaMed), I am writing in support of the Pediatric Medical Device Safety Act of 2007. We particularly appreciate your willingness to work together with all stakeholders in the development of this legislation. Your bill is an important step in ensuring expanded access to medical devices for children.

As you may know, AdvaMed represents over 1,300 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Its member companies are devoted to helping patients lead longer, healthier, and more productive lives through the development of new life-saving and life-enhancing technologies.

AdvaMed fully supports the development of medical devices for pediatric patients. Your bill goes a long way to encourage the development of pediatric devices. As your legislation is considered, AdvaMed would like to continue to work with you to strengthen your legislation to enhance development of and access to pediatric devices. For example, we have a number of proposals to highlight existing FDA regulatory tools that could improve the number of devices cleared and approved for pediatric use. We also have recommendations to improve the proposed pediatric Humanitarian Device Exemption (HDE) and propose a compassionate use provision for extremely small pediatric populations to enhance your legislation.

Sec. 522 of the Federal Food, Drug, and Cosmetic Act (FFDCA) provides the FDA with broad authority to require postmarket

surveillance for any product for which FDA has concerns. We believe that the FDA's authority under Sec. 522 is sufficient to cover pediatric patients. In fact, we are concerned that the language in your bill may unintentionally reduce access to medical devices for pediatric patients.

Finally, although we recognize and appreciate your efforts to restrict the types of studies in your postmarket database to only ''scientific'' studies, we believe the language in your bill duplicates both the database that FDA is currently working to establish and the clinical trial registry legislation and legislation currently being contemplated by the HELP Committee.

In closing, thank you once again for your work on ensuring access to medical devices for children. We look forward to working with you on these and other improvements to your legislation as the bill moves through the Committee and the Senate.

Sincerely,

STEPHEN J. UBL.

RESPIRONICS, INC.,
Murrysville, PA, August 16, 2006.

Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DEWINE: Respironics, Inc. is a global medical device company based in Pittsburgh, Pennsylvania. We are the worldwide leader at anticipating needs and providing valued solutions to the sleep and respiratory markets. We employ approximately 4,700 employees and have annual sales in excess of one billion dollars.

In our business, we often are called upon to work with pediatric patients. Based on this work, it is clear that changes are needed to facilitate an improvement in the availability of diagnostic and therapeutic medical devices for children.

Currently, a draft of a bill entitled ''To improve the process for the development of needed pediatric medical devices'' is being circulated among some Senators for discussion. After reviewing this bill, Respironics believes that the changes contemplated by this bill could help improve the availability of medical devices for children. Therefore, Respironics supports enactment of the bill.

We hope that you will join Respironics in supporting this important legislation.

Sincerely,

DAVID P. WHITE, M.D.,
Chief Medical Officer.

BREAS MEDICAL AB,
Mölnlycke, Sweden, August 17, 2006.

Hon. CHRISTOPHER J. DODD,
Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATORS DODD AND DEWINE: On behalf of Breas Medical, I would like to thank you for your efforts to expand the availability of medical devices for children. We appreciate your long-standing leadership on behalf of children and welcome your interest in ensuring that they are not left behind when it comes to critical medical advances. Our devices were developed in Europe and are available for home use in the pediatric population there. We have partnered with companies in the United States, including Sleep Services of America, and now have FDA approval for device use in adults. We are seeking approval for the use of our devices in children where there is a great need.

While children and adults suffer from many of the same diseases and conditions, their device needs can vary considerably. Cutting-edge research and revolutionary technologies have led to the development of many innovative medical products, however, very few are designed specifically for children. We support your efforts to address the barriers to pediatric device development through legislation, particularly in the following areas:

1. Improving the ability of the Food and Drug Administration (FDA) to track how many and what types of devices are approved for children each year;

2. Streamlining pediatric device approvals by allowing the extrapolation of adult data to support pediatric indications, as appropriate;

3. Encouraging device manufacturers to create products for conditions that affect small numbers of children by removing existing restrictions on profit;

4. Improving federal support for pediatric device development by creating a coordinated research agenda and establishing a contact point at the National Institutes of Health to help innovators access existing funding;

5. Improving pediatric device availability by establishing demonstration grants to promote pediatric device development, including connecting inventors and manufacturers, product identification, prototype development, and testing; and

6. Improving post-market safety of pediatric devices by allowing FDA to call for postmarket pediatric studies, establishing a publicly accessible database of postmarket studies, and giving FDA the ability to require studies longer than 3 years if needed to answer longer-term pediatric questions.

Thank you for your leadership and commitment to this issue. We look forward to working closely with you toward passage of legislation to improve children's access to medical devices.

Sincerely,

ULF JÖNSSON,
President.

SELEON, INC.,
Baltimore, MD, September 23, 2006.

Hon. MIKE DEWINE,
Russell Senate Office Building,
Washington, DC.

DEAR SENATOR DEWINE: On behalf of Seleon Inc., I want to encourage you to continue your efforts to improve access to medical therapies for children by introducing the bill, ''to improve the process for the development of needed pediatric medical devices'' this fall.

Seleon Inc., a medical device manufacturing company, strongly supports this bill. Thank you for your ongoing support of children's health and this important issue.

Sincerely,

MICHAEL LAUK, Ph.D.,
President.

ELIZABETH GLASER PEDIATRIC
AIDS, FOUNDATION,
Washington, DC, April 17, 2007.

Hon. EDWARD KENNEDY,
U.S. Senate,
Washington, DC.
Hon. CHRISTOPHER J. DODD,
U.S. Senate,
Washington, DC.
Hon. MICHAEL B. ENZI,
U.S. Senate,
Washington, DC.
Hon. HILLARY RODHAM CLINTON,
U.S. Senate,
Washington, DC.

DEAR SENATORS KENNEDY, ENZI, DODD AND CLINTON: As organizations working to ensure better health care for the nation's children, we write to thank you for your long-standing commitment to children's health and to express our support for legislation to reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) and to improve children's access to safe medical devices. We are very pleased that BPCA and PREA reauthorization language and S. 830, the Pediatric Medical Device Safety and Improvement Act, have been included in the Chairman's mark of S. 1082, the ''Food and Drug Administration Revitalization Act,'' for consideration by the Senate Health, Education, Labor and Pensions Committee tomorrow.

Over the past decade, Congress has enacted bipartisan legislation that has dramatically increased the number of drugs tested and labeled for children. The results from BPCA are extraordinary—over 336 requests have been generated for over 780 pediatric studies, resulting in over 115 new drug labels for children. Senator Dodd's BPCA reauthorization language strengthens this very successful existing program in several important ways, including ensuring prompt label changes, requiring that all study protocols and results be made public, improving adverse events reporting for children, and identifying and addressing important gaps in treatments for children's diseases. In addition, the BPCA language includes a reasoned approach to address the small percentage of drugs for which the exclusivity provision has far exceeded the incentive it was intended to provide pharmaceutical companies.

S. 993, the Pediatric Research Improvement Act (PRIA), introduced by Senator Clinton and included in the Chairman's mark, reauthorizes the Pediatric Research Equity Act of 2003 (PREA), which requires drug manufacturers to test their products for use in children. This law ensures that children are not a therapeutic afterthought and has generated impressive and invaluable safety and dosing information for children. Since the 2003 passage of PREA, 55 drugs have new or improved pediatric labeling. These drugs range from treatment of ear infections to the prevention of rejection of organ transplants. S. 993 places children on equal therapeutic footing with adults by creating the presumption that medicines coming onto the market for illnesses and conditions that occur in children will be labeled for pediatric use and be available in formulations (e.g., liquids, chewable tablets) that children can take.

The Pediatric Medical Device Safety and Improvement Act of 2007 provides a comprehensive approach to ensuring that children are not left behind as cutting-edge research and revolutionary technologies for medical devices advance. Like drugs, where for too long children were treated like small adults, many essential medical devices used extensively by pediatricians are not designed or sized for children. According to pediatricians, the development of new medical devices suitable for children's smaller and growing bodies can lag 5–10 years behind those for adults. S. 830 improves incentives for devices for small markets—while still preserving the ability to ensure the safety of new products once on the market. It provides assistance to innovators, streamlines regulatory processes and elevates pediatric device issues at the Food and Drug Administration (FDA) and the National Institutes of Health.

Despite our support for the Chairman's mark, we are disappointed that a key provision to make PRIA permanent has been omitted. As this legislation moves to the floor of the Senate, we urge you to restore the permanent authority of the FDA to ensure that children have properly studied medications as a matter of fact, not chance.

We are grateful for your long-standing leadership and commitment to improving the health of our nation's children and look forward to working with you toward swift

Committee action and passage of these pediatric therapeutic bills by the full Senate.

Sincerely,

American Academy of Pediatrics.

Elizabeth Glaser Pediatric AIDS Foundation.

AIDS Alliance for Children, Youth & Families.

American Academy of Child and Adolescent Psychiatry.

American Brain Coalition.

American Pediatric Society.

American Psychiatric Association.

American Thoracic Society.

Arthritis Foundation.

Association of Medical School Pediatric Department Chairs.

Children's Cause for Cancer Advocacy.

National Association of Children's Hospitals (N.A.C.H.).

National Organization for Rare Disorders.

National Research Center for Women and Families.

Society for Pediatric Research.

Mr. DODD. Mr. President, let me go back, if I can, to my proposal on the Best Pharmaceuticals for Children Act and the objections raised by my colleague from Colorado to it. Just for the record and so we understand what we are talking about, according to a study recently published in the Journal of the American Medical Association that looked at the costs and benefits of these pediatric trials. It showed that the overwhelming majority of drugs studied under this incentive program are not blockbusters.

In fact, the study found that less than 20 percent were. That leaves 80 percent of drugs completely unaffected by the underlying bill which the Allard amendment seeks to amend. To be clear, the proposal in the underlying bill that would adjust exclusivity from 6 months to 3 months affects less than about 20 percent of drugs studied under this program. Using data from this recent study, 80 percent of drugs studied under BPCA—those which do not fall into the blockbuster category—the 6 months' exclusivity would remain unchanged. It doesn't change that at all; only in cases where there has been over $1 billion in prior year drug sales will the underlying bill change the exclusivity to 3 months.

This is to strike a balance. Obviously, I feel very strongly, having authored this legislation, about ensuring that appropriate clinical trials occur to protect children's health. Our notion was, when we wrote the legislation 10 years ago, that the 6 months of exclusivity would be the carrot that would incentivize the industry to go forward. There were some concerns expressed at the time that 6 months wasn't going to be anywhere near enough and that we would need more exclusivity. Some in the industry suggested a year or even 3 years of exclusivity. We settled on 6 months as the appropriate balance at the time.

What happened, of course, is we had this wonderful explosion of work that occurred. It resulted in nearly 800 clinical trials involving more than 45,000 children, with new pediatric labeling information on more than 119 drugs where previously there was none. I recall the debate on this program ten years ago very well, the industry said: Six months is never going to be enough; none of us will step up to the plate on this. And they really argued very strenuously for something longer than the 6 months. In fact, the 6 months has worked well, and almost all requests issued to drug companies to conduct pediatric trials under this program have been accepted.

What I have had growing concern about is the 20 percent of drugs receiving exclusivity where the profit realized as far exceeded the carrot intended to provide to drug companies. So to strike that balance between the cost to taxpayers and the benefits to children, we are saying that where sales of a drug being studied under this program exceed $1 billion in prior years, the company can get 3 months' exclusivity.

I don't know what the right answer will be on this issue. Neither me nor my colleague from Oklahoma can say with absolute certainty. But I recall the debate 10 years ago when many said 6 months will never be enough. Six months has done very well by the industry, as it turned out.

So by striking this balance and having the sunset provision which I strongly support in this legislation—and I have from the beginning—it will allow us to review periodically how we are doing with all of this.

There is an increase in Federal spending of $50 million over 10 years as a result of the Allard amendment. I can't invoke a point of order because the impact on federal spending is outside our current budget window, but the Allard amendment comes with a $50 million pricetag to taxpayers.

I believe this program is working well. We think by adjusting the length of exclusivity from 6 months to 3 months for a limited number of drugs, we are striking the right balance. The 5-year sunset will give us a chance to assess the program again and make a judgment: How are we doing here? Are we getting more or less of what we thought we would in the process? At that time, we will make a judgment again as to how we ought to go forward.

It is not easy to strike these balances. I know my colleagues who have engaged in these debates, try to come up with answers that will satisfy the various elements and concerns various Members have. That is what Mike DeWine and I did 10 years ago and why I had such a good partner in this where we struck that balance. Mike was under a lot of pressure to have a lot more than 6 months of exclusivity. I was under pressure in saying: Why do we give them any exclusivity? So we compromised on 6 months to see what happened. We got great results.

I would love to predict with absolute certainty that what we craft here will produce those same results. I can't say that absolutely. But based on the analyses of others who have looked at this, their conclusion is this is a pretty healthy balance between consumer interests, taxpayer interests, and the needs of children. We will see what happens over the next 4 or 5 years as to whether this is continuing to produce the desired results. I believe it will. I think we will get that.

Here again, based on recent data, under my proposal, 80 percent of drugs studied under this program will see no change in the exclusivity award of 6 months. Again, for the 20 percent of drugs in the blockbuster category, they can receive 3 months of exclusivity. I still believe many will go forward, given that incentive.

So respectfully I say to my friend from Colorado—we serve on two committees together and we work well together on a lot of issues here. I respect him immensely. I do not question at all his motivations in offering this amendment. This disagreement is over the impact of his language versus the language I have crafted in this legislation as part of the committee print.

So I urge my colleagues to reject the Allard amendment and to stick what with what we put together in the underlying bill. It is a good balance between taxpayer interests, consumer interests, and the interests of children and their families.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Colorado is recognized.

Mr. ALLARD. I understand I have 10 minutes allocated to me. I would like to take 4 minutes and allocate those to the Senator from North Carolina.

The PRESIDING OFFICER. The Senator from North Carolina is recognized.

Mr. BURR. Mr. President, let me say, as Senator DODD finishes, that nobody has worked more tirelessly than he on behalf of children's health and specifically as it relates to prescription drugs. He did list a long list of people, including taxpayers and so forth.

This is about children, plain and simple. It is one group. It is our children, this country's kids. In 1997, I authored what became the Food and Drug Cosmetic Modernization Act. Prior to that, there weren't any clinical studies done for pediatric purposes. It was on the heels of that that Senator DODD and others created the exclusivity—exclusivity that Senator ALLARD is not changing. What we are changing is in the base bill and going from 6 to 3 months.

The reality is that, prior to the enactment, we didn't have companies that were studying the right dosages, what side effects there were, and whether it was effective in children. Sure, we had it for adults but not for kids. We have made tremendous progress. Under this pediatric exclusivity, though, we would cap it at 3 months. Companies that exceeded a dollar value—we pulled this out of the sky. Why $1 billion and not $2 billion? If it was $2 billion, why not $4 billion? Why not $100,000? The reality is that none of us knows. There is no expert

who can tell us what is the right amount of incentive needed for a company to go through the types of trials to get these indications for kids. Why? Because every drug is different, and, more importantly, every child is different. So if we are going to err, I suggest that we err on the side of what has worked. Eighty-seven percent of all pediatric drugs have pediatric indications. It has been the carrot of 6 months.

Members will come to the floor and vote for or against the Allard amendment. I believe it is crucial that if we err, we err on the side of what already has worked and what continues to work. If Senator DODD prevails, I hope he is right. I hope he is right because we won't know, until this bill sunsets, whether in fact the incentive wasn't great enough for companies to go through this process to find out the indications for children.

The people who will suffer because of our willingness to arbitrarily change will be the kids. That is the same group I started with—the ones we should be solely focused on. It was the kids when this was created 10 years ago; it should be the kids today. If we are going to err, let's err on the side of the kids and not use this as a way to potentially alter the profitability of an industry or a given company. Let's make sure that the true beneficiary of the work of this body is in fact the children of this country.

I thank the Senator from Colorado for yielding me the time.

I yield the floor.

Mr. ALLARD. Mr. President, I join my colleagues in recognizing the fine work that Senator DODD has done in the area of children and children's health. He recognized one decade ago how important it was to have incentives in place for drug companies to properly label drugs so they are available and a physician has some guidance when they are putting therapy out.

I particularly thank Dr. COBURN for bringing a message to the floor that reflects his practical experience, in a period of time when there weren't a lot of drugs specifically labeled for children, to help him establish the proper dosage and to be aware of the side effects that may happen to various age groups. Also, I thank the Senator from North Carolina for his comments.

I think I bring a certain degree of practical experience to this debate as a veterinarian. We are frequently put in a position where we have to recommend drugs for therapy without having had research done. You have to extrapolate what you think might happen. The drug companies will do research on those products on which they can make a profit. I am talking about veterinary prescription drugs right now. There is a plethora of medications available in the human market. Many times, in treating eye conditions or some exotic problem in a species where there isn't much of a market, we have to take the scientific literature that we know, and perhaps we know what the reaction may be in humans or maybe in some other species, where the drug company has done the research to reflect what the adequate dosage is, and we extrapolate that and predict as best we can what the reaction and how effective that drug may be at a certain dosage.

I think our children's health is too valuable to put a physician in a position where they have to make those sorts of subjective evaluations. I happen to believe the incentives we put in place a decade ago are working. That belief is substantiated by people who have looked at the program—the Best Pharmaceuticals for Children Act—and what happened as a result of that. I am not the only one who believes that. We had a study by the GAO, whose responsibility it is to look at programs to see whether they are working. They give this program a strong A. It is working. I don't think we ought to be messing with a program that has worked. Three months may be adequate, but there are a lot of other drugs that we have to still get on the market.

Several years back, during the Reagan administration—and it might have been President Reagan who said it—there was a general belief in Washington that if it is making a profit, let's tax it; if it is working, let's regulate it to death. Here is a program that is working because we have backed off on the rules and regulations. I don't think we ought to be making a decision, in light of the work that has yet to be done in moving pediatric medications to the market, to mess with this. Maybe 10 years from now it might be even more appropriate; I don't know. This is, to a certain degree, subjectivity. I think we have a huge need in making sure we have adequate medications available to treat children.

I agree with many of my colleagues that we should not be messing with a program that works, and we need to support this. I also wish to point out that this doesn't have an impact. There is not a budget point of order on this particular amendment. It doesn't add to the deficit of this country. So it is a program we can move forward on, without increasing the cost to the Federal Government.

I hope my colleagues will join me in supporting this most important amendment because it is very important, it is important to the practitioner who is trying to provide the best care that scientists will allow him to provide to patients—in this case, children. If we don't keep these choices available for the practitioner, then what happens is he doesn't have the options he should have to give the best care to our children?

So for our children's health in the future, I think we need to pass this amendment and go back to current law, which has been working so very well for us today.

Mr. KENNEDY. Mr. President, I ask unanimous consent that we be able to proceed for 2 minutes. I yield myself 1 minute and 1 minute to the Senator from Wyoming.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, for the benefit of the membership, we are having a good, substantive debate this morning. We are going to vote on this amendment in a few minutes.

Because of the meetings of the leadership at the White House, we will not be able to have votes until 4 o'clock this afternoon. That doesn't mean that Senator ENZI and I are not prepared to move ahead in lining up some other amendments. We have that intention.

After this vote, the next vote will be at 4 o'clock. If there are those who have additional amendments, we ask them to come over. We are moving along. We have several items that are almost complete, which we will include. If there are any final amendments, we hope Senators will be in touch.

I thank my friend and colleague from Wyoming for his good cooperation and for making progress on a very important bill for the health and safety of American families.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I, too, encourage people to get their amendments to us, so we can talk about the amendments. The amendment process is a difficult thing around here because it doesn't allow for some of the tweaks noticed by people who have expertise in that area. If we get to talk about them first, sometimes there can be modifications to them before they are put in. We want to move this along and have some things to vote on at 4 o'clock today. I hope everybody will cooperate on it.

I thank Senator KENNEDY and his staff and my staff who have been working together with anybody who has an amendment. They were working at 3 and 4 o'clock this morning on different things, trying to get them ironed out so that it would be possible to move the bill forward.

Mr. President, what's wrong with limiting exclusivity for blockbuster drugs? It is the exact opposite of what we should do. The whole point of the law is to leverage the large adult market for the benefit of the smaller kids' market. The effect of the cap will be to discourage companies from studying the effects of the most-widely used drugs on kids. Seventy-five percent of the drugs are not being studied under the current incentive. We need more studied, not less.

Are not companies only studying blockbuster drugs that make the most money, not the drugs needed most in kids? No. According to a Tufts University study, only about 10 percent of drugs with pediatric exclusivity are blockbusters. GAO says most products obtaining exclusivity have annual sales of less than $200 million.

Do companies get to choose the drugs they study? What is to stop companies

from ''cherry picking'' to make money, not help kids? No drug is eligible for pediatric exclusivity unless FDA requests, in writing, a pediatric study of the drug. FDA's decision is based on whether more information about safety and efficacy for children is necessary.

Doesn't the Duke/JAMA study demonstrate that 6 months of additional exclusivity is a windfall? It's been said that a cynic is someone who knows the cost of everything, and the value of nothing. That applies here. The Duke/JAMA study concluded that the financial benefit of exclusivity for blockbuster drugs often exceeded the cost of the pediatric study. This completely misses the point. This law is not about micromanaging drug company profits. It's about helping kids. In fact, the very last sentence of the study reads: ''Clearly, however, the greatest return of the exclusivity program is the benefit derived in obtaining new information relevant and applicable to the care of children, and this benefit should not be compromised.''

Companies can spend only a few million dollars on a study and get many millions in return. Shouldn't the reward be equal to the amount spent on studies? The incentive is designed to raise the priority of pediatric studies among all the competing research priorities for drug development within companies. Just covering the cost of the studies will not do it—the drug company knows it can put those same dollars into the development of a drug for adults that will earn much higher profits. Incentives work by making pediatric study more attractive than other studies for drug companies.

Aren't windfall profits unfair? No. The benefits to kids, and to society in general, from pediatric studies far outweighs the cost.

What are workability issues with the exclusivity cap? FDA says the cap has ''serious workability issues.'' It is unclear how FDA will obtain the right type of sale data or how the data's accuracy can be verified. FDA would spend lots of time litigating the validity of exclusivity decisions, and less time making drugs safe for kids.

Why shouldn't we restrict excessive drug company profit? The problem is not excessive profits. The problem is that most drugs aren't tested for kids. It is wrong to play the politics of drug pricing at the expense of kids.

Mr. ALLARD. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second.

The question is on agreeing to the amendment.

The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from South Dakota (Mr. JOHNSON), and the Senator from Washington (Mrs. MURRAY) are necessarily absent.

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from New Mexico (Mr. DOMENICI), and the Senator from Arizona (Mr. MCCAIN).

The PRESIDING OFFICER (Mr. MENENDEZ). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 41, nays 53, as follows:

[Rollcall Vote No. 148 Leg.]

YEAS—41

Alexander	DeMint	Martinez
Allard	Dole	McConnell
Bennett	Ensign	Murkowski
Bond	Enzi	Roberts
Bunning	Graham	Sessions
Burr	Grassley	Shelby
Chambliss	Gregg	Smith
Coburn	Hagel	Specter
Cochran	Hatch	Stevens
Coleman	Hutchison	Sununu
Corker	Inhofe	Thomas
Cornyn	Isakson	Voinovich
Craig	Kyl	Warner
Crapo	Lugar	

NAYS—53

Akaka	Feinstein	Nelson (NE)
Baucus	Harkin	Obama
Bayh	Inouye	Pryor
Bingaman	Kennedy	Reed
Boxer	Kerry	Reid
Brown	Klobuchar	Rockefeller
Byrd	Kohl	Salazar
Cantwell	Landrieu	Sanders
Cardin	Lautenberg	Schumer
Carper	Leahy	Snowe
Casey	Levin	Stabenow
Clinton	Lieberman	Tester
Collins	Lincoln	Thune
Conrad	Lott	Vitter
Dodd	McCaskill	Webb
Dorgan	Menendez	Whitehouse
Durbin	Mikulski	Wyden
Feingold	Nelson (FL)	

NOT VOTING—6

Biden	Domenici	McCain
Brownback	Johnson	Murray

The amendment (No. 982) was rejected.

Mr. DODD. Mr. President, I move to reconsider the vote.

Mr. KENNEDY. I move to lay that motion on the table.

The motion to lay on the table was agreed to.

AMENDMENT NO. 990

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, I offered an amendment yesterday that a number of my colleagues have spoken on, both in favor and against. When I laid down the amendment yesterday, I did not speak on it, so I wish to take some time to describe what the amendment is, why it is important, and why those who have spoken against it are wrong.

Let me describe, first of all, what the amendment is about, and let me do it, if I might, by asking unanimous consent that I be allowed to show on the floor of the Senate two bottles of medicine.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, these two bottles of medicine contain Lipitor. Most people know about Lipitor. It is a cholesterol-lowering drug. This particular prescription drug is produced in Ireland, and it is sent from that production point, in a plant, by the way, that is approved by our Food and Drug Administration. We inspect that plant, as we do others. So they produce an FDA-approved drug—this drug has been approved—in a plant in Ireland that has been inspected by the FDA. These two bottles of medicine containing Lipitor, 20 milligrams, identical bottles with a difference in color, are sent to two different places in this case but sent to many places around the world. This one is sent to the United States to be sold to consumers in the United States that want to lower their cholesterol. This one is sent to consumers in Canada for those Canadians who wish to take Lipitor to lower their cholesterol.

There is a difference. Oh, not in the medicine, not in the bottle, and not in the instruction. What is the difference? The American consumer is told: You have to pay twice as much. Let me say that again. The difference is the price. The Canadian consumer is told: You pay half the price. The American consumer is told: You pay double the price.

Now, I use the Lipitor as an example only to describe a very significant problem. We have price controls on prescription drugs in this country. Those price controls are not established by the Government. They are not established by the Congress. These price controls are imposed by the pharmaceutical industry.

I have a problem with the pharmaceutical industry saying to the American consumer: We have a deal for you; we want you to pay the highest prices in the world for prescription drugs. We are going to sell them all over the world: Italy, Japan, Germany, France, China. We are going to sell our prescription drugs, and in almost every circumstance, in other countries, we are going to give them a lower price. But to you consumers in the United States, we say: You pay the highest prices.

Let me give you a couple of examples, and I will use Canada, but I could be using any number of countries around the world. Lipitor. We pay 96 percent more. Plavix, 46 percent more. Prevacid, 97 percent more than if you were to buy it in Canada. Zoloft, 52 percent more. It goes on and on.

I said yesterday that I actually sat on a bale of straw on a farm talking to a bunch of folks, and there was a fellow in his 80s sitting on a straw bale talking about life and things, and he said: You know, Mr. Senator, my wife has been fighting breast cancer for 3 years. Every 3 months, we have driven to Canada to buy Tamoxifen because we save 80 percent by buying Tamoxifen to help my wife fight her breast cancer—we save 80 percent by buying it in Canada. So every 3 months, for 3 years, we have been driving back and forth to Canada because it is the only way we can afford that drug. He said: How do you justify that? How do you explain the

difference in price? I said: I can't. It doesn't make any sense to me.

I don't come here to be critical of the pharmaceutical industry, I come here to be critical of their pricing policy. Their pricing policies are unfair to the American consumer. Yes, the pharmaceutical industry produces miracle drugs; a fair amount of them are produced with research we pay for through the American taxpayer at the National Institutes of Health. Others are produced with the research and development done by the drug industry themselves. But I would say that miracle drugs offer no miracles to those who can't afford to buy them, and that is the point.

What is fair pricing for pharmaceutical drugs, and why is it so unfair at this point to the American people? I introduced a piece of legislation with many of my colleagues, and let me read a list of the bipartisan cosponsors, Republicans and Democrats, who sponsored the legislation that we introduced in this Congress, the very legislation I have now offered as an amendment to this bill. Let me go through a list of some of the names. Myself, Senator SNOWE, Senator KENNEDY, Senators STABENOW, BINGAMAN, FEINSTEIN, NELSON, KOHL, SCHUMER, INOUYE, BROWN, SANDERS, Senators GRASSLEY, MCCAIN, SPECTER, COLLINS, DURBIN, PRYOR, LEVIN, LEAHY, TESTER, CONRAD, MCCASKILL, JOHNSON, CASEY, BOXER, SALAZAR, CLINTON, LINCOLN, FEINGOLD. Thirty-three sponsors for this legislation that I have offered as an amendment here today.

Let me now begin to describe a few of the opponents' arguments and then respond to them. My colleague, Senator COCHRAN, came out and offered an amendment that says in order for this to be effective, the Secretary would have to certify that it poses no additional risk to the public health and safety. Well, that is an amendment that is designed to kill the bill because the Health and Human Services Secretary will not certify to anything.

Does anyone think the Health and Human Services Secretary or the FDA or anybody is going to certify that the chicken feed served to 3 million chickens with contaminated material from China, which now goes into our food source that humans are eating in this country today, that poses a risk? Or how about we say that we want them to certify that the vegetables imported into this country from Mexico pose no additional risk? Does anyone think anybody is going to certify to that? Do you, really?

I could go on at great length. Does anybody know of any circumstance in which any part of our food supply is certified by anybody saying that the import of this poses no additional risk? No. So this is an amendment designed to make this inoperative.

What my amendment does is actually make our drug supply safer with respect to the importation. Because the fact is people are now going back and forth across the border, those who can get there by car. Most Americans can't, but most are bringing prescription drugs back across the border for a 3-month supply. This makes that even safer.

I am going to go through a number of the safety areas here, but first let me say this. I understand that the pharmaceutical industry wants to continue its pricing policies. I understand that. It is perfectly understandable. I have some differences with them.

In the morning, perhaps while you are brushing your teeth or shaving, getting ready for work, you might turn on the television and what do you hear them saying on television? They say, well, you need to go talk to your doctor. You are brushing your teeth and thinking, why on Earth should I go talk to my doctor? Because the television advertisement says that you need to see if the little purple pill is right for you. You need to ask your doctor whether you ought to take the purple pill. I don't know what the purple pill is, but you get this urge that you think, maybe I should go ask somebody. If everybody is taking the purple pill, maybe I should find out if the purple pill is right for me. Maybe it is right for my colleague from Wyoming or West Virginia. Maybe we all ought to be taking the purple pill. I don't know.

If they ever describe what the purple pill does, they also have to then describe what the potential risks might be of the pill. But in most cases, the TV just says, go talk to your doctor to see if it is right for you. So we have a lot of advertising going on, and we dramatically increase the use of prescription drugs. Go talk to any doctor and ask them if patients are coming to them and telling them what kind of prescription medication they want to take because they heard it on television. Go ask a doctor, and I tell you what the doctor will say. Absolutely.

Of course, these are medicines that you can only get because a doctor has said you need them and, therefore, I prescribe them. Television advertising is creating a demand. I am not here with an amendment on television advertising, but I am observing that every morning they ask whether the purple pill, or whatever other medicine they are talking about, is right for you and that you ought to be visiting with your doctor about it.

In addition to the issue of demand, there is the issue of pricing. I don't know. Somebody doesn't have to give me five reasons or three reasons or even two reasons. I want somebody to give me one reason, just one, that says we think it is perfectly defensible that the American people ought to be charged the highest prices for prescription drugs. Or in the specific case I mentioned, we think it is perfectly defensible that the American consumer taking Lipitor ought to be charged twice as much as the Canadian consumer. Give me one reason. I am not asking for five, just one reason. I can't believe there is one person on the floor of this Senate that has the ability to construct one thoughtful reason in support of that policy.

Let me put in the RECORD a letter the AARP has written yesterday. Let me read a little bit of it:

On behalf of the AARP's more than 38 million members, we urge you to support the Dorgan-Snowe importation amendment. This amendment provides for the safe, legal importation of lower price prescription drugs from abroad.

In the quest for lower-priced prescription drugs, many Americans are already importing prescription drugs from abroad. [The Dorgan-Snowe] amendment would create a framework for the safe, legal importation of prescription drugs that will better protect the health and pocketbooks of those desperate for lower-priced prescription drugs. We are also very pleased to see that the [Dorgan-Snowe] amendment includes a number of safety requirements including inspections and measures to prevent the counterfeiting of imported drugs.

I ask unanimous consent that the entire letter be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AARP,
April 30, 2007.

Hon. BYRON DORGAN,
U.S. Senate,
Washington, DC.

DEAR SENATOR DORGAN: AARP is pleased to endorse your importation amendment to S. 1028, the Prescription Drug User Fee Amendments of 2007. Your amendment will provide for the safe, legal importation of lower-priced prescription drugs from abroad. We applaud your continued leadership on this important measure to help reduce prescription drug costs.

Brand name prescription drug prices continue to rise at unsustainable rates. AARP's latest Rx Watchdog report released in March 2007 found that manufacturers' prices for nearly 200 of the brand-name medications most commonly used by older Americans rose 6.2 percent in 2006—nearly twice the 3.2 percent rate of general inflation. These prescription drug price increases particularly burden the tens of millions of Americans who lack access to affordable prescription drug coverage.

In the quest for lower-priced prescription drugs, many Americans are already importing prescription drugs from abroad. Your amendment would create a framework for the safe, legal importation of prescription drugs that will better protect the health and pocketbooks of those desperate for lower priced prescription drugs. We are also very pleased to see that your amendment includes a number of safety requirements including inspections and measures to prevent the counterfeiting of imported drugs.

We believe the phase-in set forth in your amendment will enable better management of those important new activities. It is important that any importation system begin with Canada. However, ultimately in order to be sustainable, any importation system would have to go beyond Canada. Finally, no importation system could function if entities (particularly pharmaceutical manufacturers) were allowed to shut off or manipulate supply of their product. Your amendment grants the Federal Trade Commission the authority to prevent such abuse.

We understand that there may be attempts to limit consumers' ability to import prescription drugs by attaching a certification

requirement to your amendment. AARP believes that your amendment strikes the right balance between providing a workable system of importation while at the same time ensuring the safety of imported pharmaceuticals. Thus, we believe that any amendment that would require Administrative certification in any form would be nothing more than an attempt to prohibit the implementation of an importation system. We oppose such a change to your amendment.

As you know, our members widely support legislation that would allow for the safe, legal importation of prescription drugs. They have expressed strong interest in knowing how their elected officials vote on key issues that affect older Americans. As part of our ongoing effort to let our members know of action taken on key issues, we will be informing them how their Senators vote on your amendment when it comes to the Senate floor.

We look forward to working with you and your colleagues on both sides of the aisle to enact this needed legislation. If you have any further questions, please feel free to contact me, or have your staff contact Anna Schwamlein Howard of our Federal Affairs staff at 202–434–3770.

Sincerely,

WILLIAM D. NOVELLI,
Chief Executive Officer.

Mr. DORGAN. It is interesting to me that those who have spoken against this come to the floor of the Senate with the specter of counterfeiting. Counterfeiting exists at this point. My amendment will make it less likely. This puts in place the very safety features and the very capability to try to shut that down. But if they are talking about counterfeiting that is existing now, it is existing without these kind of safety precautions on importation.

Let me describe a man, a very courageous man named Dr. Peter Rost. He came to testify at a hearing we held on the subject of reimportation. Peter Rost was responsible for a region in northern Europe where they did this routinely. They had an approach in Europe called parallel trading. If you are in Germany and want to buy a prescription drug in France, that is not a problem. If you are in Italy and want to buy a prescription drug in Spain, that is not a problem. They have done this for a couple of decades. Dr. Peter Rost was in charge of a region in northern Europe. He said:

I never once—not once—heard the drug industry, regulatory agencies, the government or anyone else saying that this practice was unsafe. And personally, I think it is outright derogatory to claim that Americans would not be able to handle reimportation of drugs, when the rest of the educated world can do this.

This from Dr. Rost. He actually paid a price for speaking out and speaking the truth. He actually was working for Pfizer Pharmaceuticals at the time. He has had a little problem with his employer, but that is another story perhaps for another day. But Dr. Rost said it right, in my judgment.

Let me, if I might, show this quote from Tommy Thompson, former Health and Human Services Secretary. He says:

The law is this: In order to import drugs from any country, and especially Canada, I have to certify that all those drugs are safe. That's an impossible thing. If Congress wants to import drugs, they should take that provision out, because the Secretary of Health and Human Services cannot certify that all drugs coming into America are safe.

Let me tell you something about Tommy Thompson. I like Tommy Thompson. He was a Governor from Wisconsin. That's a guy with spirit. I kind of like him. In fact, I think he is thinking about running for President. I probably will not vote for him because I am going to vote for a Democrat in this coming election, but I like Tommy Thompson. Do you know what he said to me at the elevator, right outside this Senate door after he left Health and Human Services? He was getting off the elevator as I was coming on the elevator, and I had been down to see him about this issue of reimportation of prescription drugs. I said: Secretary Thompson, why don't you work with us to get this done?

He said: I can't.

He explained there are lots of things going on, including the White House makes the call on this policy, et cetera. At any rate, after he left as Secretary of HHS, he was coming off an elevator out here and I was getting on the elevator. We said hello. I like him. I think he was a good Secretary.

He turned around and said to me: BYRON, he said, keep going on that imported drug issue. You are right about that. You are right about that.

That is after he left office. He comes from Wisconsin. He knows. That is a State that borders Canada. He knows his constituents are able to just go miles up into Canada and seek prescription drugs for a fraction of the price.

Let me respond for a moment to this issue of safety because my colleague from Mississippi and others have spoken about it. David Kessler, he served for 8 years as FDA Commissioner. He is a terrific public servant. In my judgment, there has been none better than Dr. Kessler over at the FDA. Here is what he said:

[The Dorgan-Snowe bill] provides a sound framework for assuring that imported drugs are safe and effective. Most notably, it provides additional resources to the agency to run such a program, oversight by the FDA of the chain of custody of imported drugs back to FDA-inspected plants, a mechanism to review imported drugs to ensure that they meet FDA's approval standards, and the registration and oversight of importers and exporters to assure that imported drugs meet those standards and are not counterfeit.

Let me make one with respect to this. A couple of my colleagues stood on the floor and said: Well, you would create a giant bureaucracy in order to do this. That is interesting. The Congressional Budget Office actually scored this bill we have introduced. Do you know what the score was? This will save $50 billion in a 10-year period.

Mr. BYRD. With a ''b''?

Mr. DORGAN. With a ''b,'' $50 billion; just over $5 billion of that savings is to the Federal Government; just about $45 billion of that savings is to the American consumer. Is that an illusion? No, that is the score we have.

We come to the floor of the Senate and the question is asked: Whom do you stand for? Whom do you stand with? Some will say: You know what, we believe—they will not say that. I do not believe they will stand and say: We believe the current surprising strategy is right, by which Americans are charged the highest price. I don't think they will say that. I think what they will see is we think there are serious safety issues with this.

Let me again refer back to the expert who would perhaps know more about this than any other American. I have heard things read on the floor of the Senate by the assistant this or the assistant that. The last assistant we had come over to a hearing I held had not even read the bill. That is some assistant. At any rate, we don't have to worry about assistants. Let's worry about Dr. David Kessler, who I think is the preeminent authority. He said we can do this; we can do this, and it will make the drug supply in this country safer.

I wish to talk about the issue of safety. It is not as if prescription drugs are not coming into this country from other countries. They, of course, are. Our pharmaceutical industry, and others, manufacture all over the world and then they ship these drugs into our country to be sold here. But there is a law that prohibits anyone other than the manufacturer to ship them in. Lipitor is made in Dublin, Ireland; Nexium is made in France; Tricor is made in France; Actos is made in Japan; Vytorin is made in Singapore and Italy and the United Kingdom. Those are pills made elsewhere, the medicines are made there and they are shipped here. Are they safe? Sure. I believe they are safe. I believe we have an enormously safe drug supply, despite the fright that is discussed on the floor of the Senate about counterfeiting.

Is counterfeiting an issue? Sure, it is. It has nothing to do with this subject. Counterfeiting exists now and we have to take action and steps to fight it and we should fight it aggressively. But the fact is, this legislation that we introduce has a range of safety features that will guarantee the safety of FDA-approved prescription drugs that are imported into this country.

First of all, we provide that only FDA-approved medicines with a ''chain of custody'' will be sent into this country. Dr. Mark McClellan, who used to head the FDA, and I was very critical of him because he continued to speak as if he represented the pharmaceutical industry instead of regulating it as head of the FDA, he and I had substantial differences, but even he said the chain of custody in Canada is safe, almost identical to the chain of custody for prescription drugs in the United States.

If that is the case, and he said it, then tell me with respect to this risk,

I go to a little one-room drug store in Emerson, Canada, with a woman named ''Sylvia'' and a number of other senior citizens. We take a little bus up to a one-room drugstore in Emerson, Canada, and they bring their prescriptions.

That drug store has a licensed pharmacist, as the drug store a few miles south of the border has, a licensed pharmacist and a chain of custody from the drug manufacturer to the wholesaler to the retailer to the drug store. We go to that drug store and Sylvia and her friends buy prescription drugs at a fraction of the price they would have bought it in Fargo, ND, that morning. Tell me, is there a risk in that transaction? The answer is no. Don't represent there is because there is not.

The chain of custody is nearly identical. I am speaking now of Canada. Tell me there is a risk and you are wrong, there is not.

All the protestation on the floor of the Senate on this issue is protestation in support of the pharmaceutical industry. I like the industry. I have been helpful to them. I support research and development tax credits to find new prescription drugs. I have done a number of things to say I want us to be able to have a successful pharmaceutical industry in this country. But I am not willing to go so far as to say it is OK to me, I will be quiet if you decide the pricing strategy is we are going to price our prescription drugs at the highest prices for the American consumer. I will not sit in this chair and say it is fine with me. It is not, and that ought not be fine for any Member of the Senate. It should not.

Mr. BYRD. No. No.

Mr. DORGAN. Let me make some comments on safety. One-quarter of the prescription drugs taken in this country are produced outside this country in foreign manufacturing plants. In the last 5 years, the FDA has inspected more than 850 foreign drug factories in 41 different countries. The drug industry wants to take advantage of the global economy to manufacture their drugs in lower cost countries, but they do not want a licensed U.S. pharmacist and drug wholesalers to be able to take advantage of the global economy to get the best price for the American consumer.

Let me say that again. The pharmaceutical industry wants to take advantage of the global economy for the purpose of their manufacture and profitability, but they do not want a licensed U.S. pharmacist or licensed wholesaler to be able to access those same drugs from a licensed wholesaler or pharmacist in another country in order to pass along lower prices to the American consumer. I do not think that is right.

We have addressed all the issues that have been raised by two former Secretaries of Health and Human Services, saying in order for me to certify, we need to have this and that. We have addressed those safety issues in this legislation. Yet if you listen to the opponents who stand on the floor of the Senate with the talking points, there are safety and security issues and all these issues—I mean I have gotten the talking points, too, from the pharmaceutical industry. Heck, if I were in their position, I would want to keep this situation as long as possible. You have a good deal, don't give it up.

But one of my colleagues yesterday, speaking on the floor, said: The people who are offering this amendment—and again this amendment goes from Senator KENNEDY to Senator MCCAIN to Senator GRASSLEY to Senator STABENOW back and forth, Republicans and Democrats. One Senator, one of my colleagues, stood up and said there are political motives.

I said I hope you don't mean that, and I hope you will withdraw that. This is a thoughtful serious debate. There are plenty of people who feel strongly in opposition to my amendment. Fine. But then you should stand and debate the proposition that you support. We support the current situation. We support the circumstance in which a pricing policy that prices the prescription drugs higher for the U.S. consumer is already with us. That ought to be the proposition you stand and support.

You ought not stand and say there are significant safety issues here because that is not the case. It is not.

There is much to say, and a number of my colleagues will continue to debate this issue. My own view is this is a hard issue to get passed on the floor of the Senate. I say that having had some experience with it.

I must say I admire the pharmaceutical industry. They have been tough opponents. They feel strongly about their profitability. They say a couple of things. No. 1, this is unsafe. It is not. No. 2, it would somehow exacerbate counterfeiting. It will not. Counterfeiting now exists. We need to address that, but this would in many ways make the supply of drugs safer. They say a number of other things they believe—that this would cause the American people to change their buying habits in ways that would be unhelpful to them. They believe you do not have a chain of custody that you can control or see that is transparent. That is not true.

You know, I mentioned earlier about this issue of the industry itself. I want the pharmaceutical industry to succeed. They succeeded. This has been a very successful industry. They have made a great deal of money. But on this issue of research and development, I want them to engage in research and development. We are doing it here in the public sector of the NIH. We turn that material over to the pharmaceutical industry. They do research and development. Good for them. They spend a massive amount of money on promotion and development. I think that is of some concern for a number of people, but I am not here saying I do not want the pharmaceutical industry to succeed. There are those who also say, in addition to safety and other issues, they will say, all right, if you do not allow a pricing policy that prices prescription drugs at the highest level for the American consumer, it will mean less research and development by the pharmaceutical industry.

The fact is, more research and development has gone on in other countries in which they charged lower prices for the same prescription drugs. So how does that hold water? It does not. My hope is, at long last, perhaps, this Senate will stand up for the interests of the American consumer. At long last, we can put to bed these specious arguments about safety because they are not applicable. Read the bill. These arguments about safety are not accurate. Let's put to bed this connection between counterfeiting. It is not accurate. Let's also stop talking about how this would shut off research and development. That is not accurate.

Let's talk about what this bill would do, what this piece of legislation, this amendment we have now offered is. It would save about $50 billion over 10 years, $5 billion a year. It would probably require the drug industry to reprice for sure because, the fact is, if they are pricing at the highest levels to the American people, and they say that is the only way they can recover their costs, perhaps others ought to be paying more to recover costs. I don't know. I am saying that the industry, I believe the top seven U.S. pharmaceutical companies, a couple of years ago made $34 billion together. The industry has done very well. But there are a whole lot of folks in this country who haven't.

It was about 9:30 one night in a tiny town north of Highway 2 in North Dakota. I had a town meeting. At the end of the town meeting, an older woman came up to me, and she was probably in her early eighties. She said: Mr. Senator, may I speak to you? I said: Sure. She grabbed my elbow with her hand. She began to speak. Her eyes welled up with tears and her chin began to quiver. She said: I am in my eighties. I don't have much money. She said: I have got heart disease and diabetes. My doctor prescribes medicines for me that are too expensive. I cannot afford them. Is there any way you can help me, Mr. Senator? Is there a way you can help me?

This woman, with tears in her eyes, was asking: Is there someone who can help me manage this disease of mine because I cannot afford these medicines?

We have taken steps to try to be helpful. I might say that some in the drug industry have taken steps by offering programs to low-income people. It is not enough. But I commend those who have and recognize it. But we should not have to do that in this country. We should not have the highest prices for prescription drugs. We should not have an 80-year-old woman driving

to Canada to pay four-fifths less in cost for Tamoxifen to treat her breast cancer. That should not happen.

So let's do this. Let's create a regime of safety—which we have done. Wonder about it? Go talk to Dr. David Kessler. You find a better expert, you tell me his name. We have created a regime of safety here that will work. Then let us decide to proceed, as Europe has done, as others have done, to allow the global marketplace to work for real people, to work for ordinary folks, not only the big interests. The big interests always do well. At the end of the day, when all of the dust settles, and all of the shouting is over, guess who almost always wins. Yes: Them that's got is them that gets and I ain't got nothing lately. I think that was Ray Charles.

Isn't that always the case? When the dust settles, the big interests always win. Let's hope when the dust settles here tomorrow morning, and we have a vote on something that is important, is something that will help a lot of American people, millions, tens of millions, hundreds of millions, let's hope when the dust settles here, ordinary Americans will say, you know what. We won today in the Senate. Hallelujah, we won a vote in the Senate. Let's hope that is the case tomorrow morning.

I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. SANDERS. Mr. President, there is not much I can add to the brilliant remarks made by Senator DORGAN. I think he, in a very comprehensive manner, made clear why the Senate and this country should move to prescription drug reimportation. I think he very ably answered the objections that we know are sure to come and made the case as well as could be made.

I want to touch on some personal reflections on this issue. Some years ago, as the Congressman then from the State of Vermont—and I live an hour and a half away from the Canadian border. My State borders Canada. Some years ago, I put together what, in fact, turns out to be the very first bus trip to take constituents over the Canadian border to buy low-cost prescription drugs.

All of us have days which are transformative where something happens we will never forget, and that is the day I will never forget. On that day we took a busload of Vermonters, mostly women, many of the women struggling with breast cancer. We went from St. Albans, VT, to Montreal, Canada. I will never forget the look on the faces of those women who were struggling for their lives when they bought breast cancer medicine at 10 percent of the cost they were paying in the State of Vermont. The drug was Tamoxifen, a widely prescribed drug for those people who are struggling with breast cancer.

These women walked in fighting for their lives, many of whom did not have a lot of money. They walked in there and they could not believe, literally could not believe, the cost of that medicine which they needed to keep them alive. At that moment some years ago—it may well have changed since then—the cost was one-tenth what it was in the United States of America.

The question is a very simple question: How do you have a drug manufactured by a company, manufactured in the same factory, put in the same bottles, sold in Canada, in some cases for one-tenth the price that same medicine is sold in the United States of America? How possibly can that happen?

Now, as it occurs, I am not a great fan of unfettered free trade. I have very serious concerns about what our trade policy is doing in terms of throwing American workers out on the street, moving plants to China and other low-wage countries. But I am always amazed that on the floor of Congress, when it comes to representing the interests of multinational corporations, people are always speaking about how great unfettered free trade is; it is not a problem; American workers going down the street; workers in China paid 30 cents an hour. That is okay. That is part of globalization.

Well, why isn't it part of globalization that prescription drug distributors and pharmacists can pick up FDA safety-approved medicine at a fraction of the price they are currently forced to pay, and lower the cost of prescription drugs in this country very substantially? Why is that not a process of globalization that every Member of the Senate should be supporting?

We should not kid ourselves as to what this debate is about. I think most Americans understand that large multinational corporations have enormous power over the Congress. You have big oil running up recordbreaking profits, receiving tax breaks and corporate welfare. You have credit card companies with tremendous power over what goes on in Congress, able to charge Americans 25, 28 percent usurious interest rates. You have insurance companies blocking national health care efforts so all of our American people can have health care as a right of citizenship. But at the top of the list of powerful, greedy special interests, at the top of that list, that very impressive list, stands the pharmaceutical industry. They are at the top.

So when you talk about powerful interests, look at the pharmaceutical industry and the impact and the power they have in terms of what goes on here in Congress. Since 1998, the pharmaceutical industry has spent over $900 million on lobbying activities; $900 million since 1998. That is more than any other industry in the United States of America.

It is hard to believe, but there are now over 1,200 prescription drug lobbyists right here in America, many of them right here on Capitol Hill. That amounts to more than two lobbyists for every Member of the House and the Senate. They have us well covered. These people are paid top dollar as lobbyists. These are former leaders of the Republican Party, former leaders of the Democratic Party.

Let me tell you, they are hard at work today. They will be hard at work tomorrow. What they have done successfully, year after year after year, is when an effort comes up in the House and an effort comes up in the Senate, they descend like locusts into the offices of Members of Congress and say: Don't vote for change. Keep the status quo alive. Make sure the American people continue to pay the highest prices for medicine in the entire world.

Since 2000—I don't know if you are supposed to talk about these things on the floor of the Senate. I will. Since the year 2000, the pharmaceutical companies have contributed almost $250 million in campaign contributions. Let me repeat that. Since the year 2000, the pharmaceutical companies have contributed almost $250 million in campaign contributions.

What this debate is about is not just whether we are going to lower the cost of medicine in this country and save billions and billions of dollars for the consumers of our country, for people with acute and chronic illnesses, for our seniors; it is also about whether the Congress of the United States is, in fact, prepared to stand up to the most powerful, the greediest special interest in the United States of America.

In my view, the time is long overdue for us to begin to make some fundamental changes in our prescription drug policies in this country. The time is long overdue for us to lower the price of medicine for our people, which not only will help people, of course, pay for their prescription drugs, it will lower the entire cost of health care in the United States.

We spend far more money per capita on health care than does any other country on Earth. If we lower the cost of prescription drugs, we will have an impact on that.

Tomorrow I will be speaking at greater length on this issue, but I think the arguments are so clear that prescription drug reimportation makes sense. The idea, as Senator DORGAN has mentioned, that somehow we can import tomatoes and lettuce from farms in Mexico and in Latin America, that is okay, but we cannot reimport prescription drugs from Canada with FDA regulations, that is impossible, makes sense to nobody at all. Food coming in from China, no problem; FDA-regulated prescription drugs coming from Canada, oh, my word, it can't be done. Give me a break. Of course, it can be done.

What this issue is about is not drug safety. What this issue is about is the profits of the pharmaceutical industry and the enormous power they have over Congress. Now is the time for us to say to the drug companies: You have dominated what goes on year after year after year. You, in the drug industry, wrote the prescription drug Medicare bill. You have resisted year after year every effort to reform how we price medicine in the United States.

Maybe the year 2007 might be the moment in which Members of Congress have the courage to stand up and say enough is enough. Let's support the men and women and children, the seniors of our country. Let's lower the cost of prescription drugs. Let's pass prescription drug reimportation.

I yield the floor.

The PRESIDING OFFICER. The Senator from West Virginia.

Mr. BYRD. Mr. President, thank God for BERNIE SANDERS, the Senator from Vermont. Thank God. Sail on, brother.

I thank the Chair.

Mr. SANDERS. I thank the Senator.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I will have a lot more comments on this bill at a later time. In light of the comments by the Senator from North Dakota about the importance of reading the bill, I wasn't sure that I had read the most recent copy of it. I think I have the most recent copy of it now. It is a fascinating 140 pages that is being attached to our 300-page drug safety bill. The reason I am checking it is because in the past we have noticed some strong implications for safety problems with drug importation, and I want to make sure we are not opening the door for even more safety problems. I had hoped that the bill on safety wouldn't have to get into the safety of imported drugs, but I can see that is not the direction we are going. I am more than happy to address it.

I am fascinated by the discussion today because the people who normally are talking about free trade are now talking about some restrictions. That would be my side of the aisle. Those who normally rail at any kind of opening of the market to anyplace outside of the United States are the ones who are supporting this bill. It is kind of a reversal of situations.

I have heard the Senator from North Dakota talk about the way the Canadian Government is subsidizing the grain in that country and how that gives them an unfair advantage in the United States market and how we have to be sure that doesn't happen. Yes, the Canadian Government subsidizes. Yes, the Canadian Government gives an unfair advantage to their citizens. On drugs, the Canadians do some interesting things, too. They are a very small, limited market compared to the United States.

Sometimes in business when you are trying to price things, you say: I could pick up a little bit more in the market if I changed my price a little bit. But I am only willing to go after the fringe in order to do that. That is kind of what has happened in Canada. Canada has made it a little more difficult for the drug companies because they say: We are going to negotiate the price. I love that word ''negotiate.'' Normally that means there is a little give and take on both sides and some advantages that are picked up on both sides in order for the outcome that is derived.

In terms of pharmaceuticals, usually ''negotiation'' is the code word for ''price fixing.'' That is what they have done in Canada. They have fixed the price. If you want to be able to sell your drug up there, they will tell you what bid you better come in at and they are willing to have various pharmaceuticals bid against each other for the right to enter that fringe market, a small portion of what is in the United States but a potential customer. If you can cover your costs and pick up a few more sales, perhaps you can increase profits. It is a little accounting trick, but it happens. But they negotiate the price.

There are five drugs for heart that do similar things. They make the five drugs for heart bid against each other. That means one or two of them will win the bid. If your doctor prescribed one of the other three in Canada, you are out of luck. The decision by the doctor is taken away because you will get a good price on the pharmaceutical that may not be quite right for you, but it will be cheaper than what you could have gotten. That is not the way we work it in the United States. We try to have competition between all of the different products and hope that brings the price down.

There is some positive indication that it does bring the price down. We have the Medicare plan D. When they did the calculations on how much that was going to cost, it was considerably higher than what it actually came in at when there was competition among the providers, who in some cases represent more people than Medicare or Medicaid or the veterans and negotiate prices, but they negotiate realizing that we are forcing them to provide all of the pharmaceuticals, not just one or two out of five. If they are providing a plan, they have to provide for the prescription drugs.

When I was doing hearings across Wyoming, I had a little surprise almost at every meeting that I had to explain Medicare Part D. That was somebody saying: I can't get the prescriptions I really want. I was doing all of this promotion before Part D even went into effect. So I knew something was wrong with that kind of a response. It occurred to me that maybe those were veterans. We negotiate the price on drugs for veterans. That means when the Government is doing it, they have to say: You know, I don't think your price is low enough so we are just not going to make that available to our people.

Did you know that a whole bunch of veterans are taking prescriptions under plan D because they can't get what they want under veterans? It is an interesting situation. When you negotiate these things, you change some of the dynamics and you do not make everything available. I don't think we in the United States are going to settle for just having some, although if we can tap the cheap one in Canada where they fix the price, that will lend an advantage to people in the United States. I am ready to admit that. I am ready to admit if we didn't have restrictions on ethanol and subsidies in this country, we would bring in a whole bunch of ethanol from Brazil. But we are going to protect the ethanol. Again, it is a different group of people who are talking about that than are talking about drug importation.

Let me get back to drug importation because that is important. The Senator from North Dakota several times—in fact, all the time—used to say ''where are all the dead Canadians'' when he was talking about safety. That is what my colleague from North Dakota used to come down to the Senate floor and say when he was talking about importation. He always asked that question. It may have escaped the notice of those of us in this body that he didn't ask that question anywhere in yesterday's debate or today's debate. Why not? Because two summers ago, five people in Hamilton, Ontario, died from taking counterfeit Norvasc. Norvasc is a blood pressure drug taken by millions upon millions of people who rely on it for their health and well-being. Since so many people take it, it is a target for counterfeiters looking to make a quick buck. I know he did say that counterfeiting is going to happen anyway. Probably. It happens in virtually every industry, and there are some countries that actually specialize in it. But imagine opening an opportunity for counterfeiters, an opportunity for them.

In the portions of the bill I have gotten through already, I know there are some pretty tight restrictions on who can be an exporter and who can be an importer and how packages will be labeled and all of those sorts of things. It is a marvelous effort to try to tighten it up so that what you buy is what you think you are getting. But how many of us, when the program was to first start, would know what to look for or even who to order from in order to be sure the drugs we are getting are safe? How do you do that? It is a tremendous opportunity for counterfeiters. We already have a problem with counterfeiters. There is no way you can write off the counterfeit argument.

I ask unanimous consent that I be able to show some three-dimensional objects on the Senate floor, the same as the Senator from North Dakota.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ENZI. I will leave this on the desk so people can take a look at it. This is the Norvasc product with which the Canadians had a problem. It killed people. I want Members to take a look at the packaging. I have the external packaging. I have the internal packaging. I have the pills themselves. I challenge anybody to see the difference. We are going to put some special labels on anything that gets shipped into the country. I am sure nobody would ever be able to counterfeit any labels that were coming into the

country. It just couldn't happen. There are now dead Canadians, and it saddens me to say that I believe there will be even more. These unfortunate individuals got their fake pills from a brick-and-mortar pharmacy. If that is what is happening when you buy drugs in person in Canada, who knows what you might get when ordering from a Web site that says it is in Canada but could really be based anywhere in the world.

In fact, some of the drugs that have been intercepted by the FDA have come through Canada but actually were from Saudi Arabia. Communication worldwide is transparent these days. Whom you think you are ordering from is not always whom you are ordering from. Right now that practice is referred to as hiding the maple leaf.

I would like to invite my colleagues to visit with me when I am finished my remarks. I have these pills I would like them to take a look at. There are other examples, too.

So anybody who holds up two bottles and says, this one is this and this one is this, they can't be sure if the one that is being imported is really from the country they are talking about. It has to be a concern. That has to be tightened up. There have to be some ways people can really tell.

There is also a difference between whether you are importing for an individual or you are importing for a pharmacy. If you are importing for a pharmacy and they get a counterfeit load, it is not just one person who dies. It is the whole community, everybody who is taking that medication. So there needs to be some concern with these things.

As I said earlier, we all want to have affordable drugs. We would like to bring down the cost of medicine every way that we possibly can. But a counterfeit or tainted drug is unsafe at any price.

I want to add another thing on the counterfeit drugs. You can take the pills and you can grind them up and do a chemical analysis of one pill against the other, and they will come out identical. Now, part of the problem is the way you put these together to make them dissolve properly so what you need in your bloodstream gets into your bloodstream.

A number of the imported drugs that have been confiscated are shown they will not even dissolve. If you take a pill, and it goes completely through your whole system, you could die. It is a serious problem. It looks good, it even checks out good, but there are processes for putting these things together.

From my brief reading of the bill, I am also worried about some of the biologic information that may be in there that could be imported as well.

The Food and Drug Administration Revitalization Act is about restoring the trust of the American people in the FDA. That is where it belongs. We should have a lot of concern.

There is an amendment that is going to come up everybody is working on right now to make sure it would work, and it talks about some increased safety with food. Now, food, some of it, such as tomato packaging, is pretty well there. It is not put in another container. It is hard to fake. But there can be problems. We had problems with spinach in this country. We have a big problem with pet food right now, and it is because of China.

China—how much do you trust them with your drugs? We have been trusting them with our pet food, and they are killing our pets. It took a little thing called melamine that increases the protein count in the food. It does not increase the protein, it just increases the protein count. It makes it look like a much richer food than it is. Unfortunately, it kills. Unfortunately, they have not just been using it in pet food; they have it in their regular food chain, and children—young children—got it, and the children died. When they checked on it, they found out they died of starvation, even though they had what should have been a good protein diet. There was a little melamine in it, and it was starvation rather than poisoning.

But if they do that to food products, how much would we worry about drug products that come in from there? I know there are some limitations on where they can come from, but if they get into the European Union, there does not appear to be any constraint on it then, and it could be transferred on over to the United States. So throwing our borders open to drug importation would, instead, falsely place trust in criminals trafficking in illegal pharmaceuticals.

I think the American people deserve better. I hope we do not make this move at this point in time, and that we constrain the bill to those things we know will add safety to our pharmaceuticals and medical devices and things for children in this country.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from New Hampshire.

Mr. GREGG. Mr. President, I join with the ranking member of the HELP Committee—the Health, Education, Labor, and Pensions Committee—in raising the concerns and agreeing with the concerns he has raised about the reimportation proposal which has come forward from the Senator from North Dakota, which has been debated on this floor a number of times.

The issue, of course, is the safety and efficacy of products which Americans buy. The FDA has been given the responsibility and has executed that responsibility extraordinarily well to make sure when an American citizen buys a pharmaceutical product or a medication, it is what it says it is and it does what the doctor prescribes.

If you start buying medications internationally, you are in the position where you have no capacity for the FDA to monitor that purchase. So the drug may be represented to be an FDA-approved drug, but it could easily not be. In fact, case after case has been discovered of adulterated and changed medication coming into this country under the representation the medication which is being purchased is medication which has been approved by the FDA. So you are basically opening up a massive loophole in the area of safety for the American citizenry.

Now, the demand for this comes from the cost of the drugs. People want to be able to go across the border to Canada, which is obviously a very sophisticated nation, and buy a pharmaceutical product there, which costs significantly less than the same pharmaceutical product may cost in the United States. That is a natural instinct of the market economy and of people. But critical to this exercise, of course, is the ability to get a safe drug.

If you go across the border, and you buy a pharmaceutical product which is alleged to be one thing, and it turns out to be another thing, the damage it causes you is going to be economically much more significant than the savings which you may have accomplished by purchasing that drug across the border.

Also, it should be noted that with the Part D pharmaceutical program which we now have relative to Medicare, the pressure—because pharmaceutical products are now insured and people receive them under the insurance plan as created under the Part D program, which has been an extraordinary success to supplying pharmaceuticals, though its cost remains extraordinarily expensive for the next generation of Americans—but pharmaceutical products are now available under an insurance program to most American seniors, and, as a result, if you are a senior, one of the people most likely to use a large number of drugs, and most often are on a fixed income and have problems purchasing drugs as a result of the fixed income situation—those issues were addressed by Part D to a large degree relative to the senior purchasing drugs; and it did create the ancillary problem of creating a huge cost which has to be borne by the next generation—but relative to the supplying of drugs, the pressure which was forcing people to take the chance of purchasing a drug internationally has been relieved to some degree, significantly in the area of senior citizens.

I proposed language which would create a safe pharmaceutical approach, where you would create an Internet pharmacy approach, where you would create a regime under the FDA where people could go on the Internet and buy pharmaceutical products knowing they have been approved by the FDA.

Today, unfortunately, that is not the case. If you go on the Internet, and you purchase something through a pharmaceutical firm off the Internet, you do not know whether that product—even though it may be represented to be FDA-approved—is FDA-approved because there is no way to certify the

site you are purchasing from is an FDA-approved supplier.

So this reimportation bill is essentially going to create an atmosphere where those Internet pharmacies are going to become basically the ''wild west'' of supplying drugs in this country, and you are going to see people going on to these Internet pharmacy sites and purchasing drugs they think are being represented as an American-approved drug that has been reimported—and is at a lower price—but may actually be a totally adulterated drug which will do significant harm to you.

We have seen instances of that already—dramatic instances. Case after case has been reported of people being significantly harmed and in some instances dying as a result of buying pharmaceuticals off the Internet that turned out not to be what they were represented to be from international sites.

So at a minimum, this reimportation proposal, which has received significant support in the past because it has a motherhood name on it—even though it might be actually creating significant problems for children and for other people in this country as a result of the risk it puts people at—at a minimum, this proposal should be subject to creating some sort of a regime where FDA has the ability to monitor and to approve and to make available to the public the knowledge that Internet pharmaceutical sites have been approved by the FDA. That is what my amendment does. It tries to address that.

So we should not move forward precipitously in the way that is proposed by the Senator from North Dakota. We should not be supporting this simply because it has a nice name on it and because he can hold up two bottles which are the same drug but costs differently in a managed economy in Canada and a market economy here in the United States. We should, rather, set up a structure where FDA can be sure that when you buy that pharmaceutical product through an Internet site that is international or from a Canadian pharmacy, that you are getting what they claim you are getting, so when you take that drug, you benefit from it and are not harmed by it.

This all, however, gets to a bigger issue. Probably, there is not time right now to go into it in depth. But the bigger issue is, where do pharmaceutical products come from? Where do all these amazing products, the biologic products that are saving lives in this country and are creating such a much better lifestyle come from? Remember, they do not come from trees, and they are not grown in North Dakota in the sugar beet fields. They are developed through processes which involve years—years of investigation and research.

The average pharmaceutical product in this country takes 12 years and $800 million to bring to the market. Think about that: 12 years and $800 million before you can produce a product Americans can take. That is a pharmaceutical product. If you are getting in the biologics area, which is a much more complicated area, it takes even longer. It is even more complex, and in many instances it is even more expensive.

It is these products that are changing the life expectancy of people and making the quality of life of people so much better. We have basically gone from a medical regime in this Nation where invasive action was always the first call, was always the first event, where you basically went under the surgical knife, to a regime where you are given pharmaceuticals or biologics to try to address a very serious illness. It is a huge step, an exponential step in the direction of better health care and a better lifestyle for Americans and for the world.

Where are these products developed? Well, they are developed here in the United States. Why are they developed here in the United States? Why are almost all the major pharmaceutical breakthroughs and all the biologic breakthroughs coming in the United States? Because we have a market system which allows people to take the risks to develop those products.

We do not fix prices, as they do in Canada or in England, at a rate that is so low that nobody would be willing to invest in developing that product because the return on that investment is too low. We allow people who make the investment, who take the risk, who put the 12 years in, who invest $800 million, to get a reasonable return on their investment and on their effort. As a result, we have the explosion in advances in technology, in medical technology, in biologics, and in pharmaceuticals.

It is a result of the fact that people who want to take that risk, and who have the ability to pursue that type of opportunity to make life better for people by creating these pharmaceutical products and these biologic products, have the capacity to get resources to do it. It is called capital markets.

Now, capital does not flow for goodwill. People do not invest in things because it makes them feel good, in most instances. People invest where they are going to get the best return on the dollars they invest, or a reasonable return on the dollars they invest. So we have to maintain an atmosphere in this country where people are willing to put money—cash, capital resources—into the investment and research and development of pharmaceutical and biological and device products.

But if you listen to the other side of the aisle, almost every proposal they come forward with seems to be of the view that these products are grown in some wheatfield in North Dakota, that they do not take any effort, that they do not require any capital, they do not require any expertise, research, or time. All they require is to be price fixed, to be limited in their ability to be distributed relative to the price that is charged.

Time and again, the other side of the aisle has come forward with proposals which basically undermine the incentive for capital to flow into these research areas. Believe me, if capital is disincentivized from going into these areas because they do not get a reasonable return, they will go somewhere else—they will go into developing software, into gaming, into whatever it is that happens to give them a reasonable return, into investing in some other country's activities in some area.

Capital does not flow out of goodwill into pharmaceutical production, into biologic production, into device production. It flows into those accounts because they expect a reasonable return.

Now, sure, the countries of Canada, England, and the European common market, to some degree, are living off of the fact that we give people a reasonable return on our pharmaceuticals and biologics in this country. That is absolutely true, and it is reasonably disgraceful. In fact, in Canada, they threaten to take people's patents away if they don't—they basically capture American patents if they don't sell these drugs at a price which nobody would have invested in them in the first place to produce them were the price fixed at that level. But that is their policy.

Now, we could subscribe to that policy, which is what the other side of the aisle wants us to do. They proposed it in Medicare negotiations, they proposed it now and passed it here in the child drug review. They proposed it in this reimportation, and they proposed it in the negotiated language relative to Medicare, and in biologic generics. In all of these areas they are basically saying: Well, drugs must appear in the marketplace. We don't have to be concerned with the fact of getting capital into the investment exercise. We don't have to be concerned with the fact that it takes years and years to research these products and hundreds of millions of dollars to bring them to the market, they just appear. We can basically, for lack of a better term, kill the goose that is laying the drug or the biologic or the pharmaceutical or the device that is saving people and not worry about it.

Well, that is not true. If you were to follow all of the proposals from the other side of the aisle, or even a significant amount of them, we would see investment in this area start to dry up. We would see a contraction of the production of pharmaceuticals that save lives, of biologics that save lives, of devices that save lives. We would see fewer and fewer of those coming to the American people and to the world because people wouldn't invest in that activity any longer, or the investments would be significantly curtailed because money would flow in other directions.

This concept of the marketplace totally escapes the other side of the aisle. This concept that drugs have to actually have some flow of capital behind them to be produced because it takes so long to get them to the market, and it takes so much money to actually research them—and that is especially true in biologics and equally true in devices. It totally escapes the other side of the aisle. Their idea is, we have a good line, we have a motherhood statement, let's let people go buy the drugs somewhere else at a price that is fixed at which nobody would have ever produced the drug in the first place if that was the price. Let's negotiate so we have a regime of price setting at the Federal level, which basically eliminates the capacity for that drug to be competitive.

Let's create a biologic generic which basically wipes out the capacity of the true biologic to actually come to the market and be successful. Let's create an atmosphere where testing on children of the drugs will basically not have a fiscal return which will make it worthwhile to test them on children. Let's do all of those things in the name of the motherhood language of getting a better price for drugs for Americans, ignoring the fact that what you are actually going to end up doing is dramatically limiting the number of drugs coming to the market for Americans, and therefore significantly impacting the quality of life of Americans and our ability to advance the dramatic and revolutionary activity that we are seeing in bringing biologics to the marketplace, which are basically curing and have the potential to cure diseases which have been extraordinarily threatening to the American population for so long.

It makes no sense, if you look at the substance of the issue, what they are proposing. It is totally inconsistent. They are saying they are doing this to help people. What they are actually ending up doing is harming not only the people of today who won't be able to get the drugs because they won't be produced but people in the future because the drugs won't be brought to the market. There is a blindness to the fact that market forces are at work. I guess it is just a function of the fact that you want to get out a good press release, so you are going to send it out. Of course, anybody who takes the position I just outlined is immediately demagogued, and the pejorative tool of the drug industry is thrown out there.

Well, I am hardly that, since I was one of the few people in this Chamber who actually aggressively opposed and tried to stop the Medicare Part D Program, which was the biggest windfall the drug industry ever got and which was voted for by many of my colleagues on the other side of the aisle and which ended up putting an $8 trillion bill which is unpaid for onto our children's future.

More importantly, the reason I take the position I take is because I believe very strongly that America should not give up its lead in one of the industries where it is at the cutting edge and where it is producing jobs and where it is producing the intellectual capital that is going to keep us a vibrant, strong economy. In addition, we should not give up an industry or undermine an industry and geniuses and creative individuals who are producing products which are saving lives and are giving people a better livelihood. So I am not going to sign on to these various jingoistic proposals which are brought to the floor for the purposes of putting out good press releases about how I did this or that for motherhood at the expense of undermining the quality of care for future generations by basically limiting dramatically the ability of people to get capital who want to be creative, who want to invest, and who want to do research in the area of producing biologic products, pharmaceutical products, and medical devices.

That is why I take the position I take, to say nothing of the fact that if you start haphazardly importing products from the Internet and from countries such as Canada, as strong as Canada is, without any FDA oversight or approval of those products, you are going to harm a lot of people at the end of the day. A lot of people are going to be hurt, and some people are going to die as a result of buying products which have not gone through FDA approval and which are not subject to FDA oversight because they are bought from a pharmacy or a provider in Canada, and that product may have come out of India or it may have come out of Afghanistan. It may have come out of Pakistan. It may be adulterated, and it may kill. The same can be said by a factor of 10 relative to purchasing on Internet pharmacies.

So there are some big issues at play. There are big issues at play relative to the future of the health of Americans on the issue of importation, on the issue of negotiation and Medicare, on the issue of biologic generics, and on the issue of making sure that children are adequately tested relative to the application of drugs which are brought to the market. There are big issues relative to safety and big issues relative to whether this country remains on the cutting edge of producing products that help people and give them a better lifestyle with a biological, pharmaceutical, or medical device. We shouldn't just pass these proposals willy-nilly for the sake of putting out a nice press release.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from South Carolina is recognized.

Mr. DEMINT. Mr. President, I ask unanimous consent that the pending amendment be set aside.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

AMENDMENT NO. 1018

Mr. DEMINT. Mr. President, I have an amendment at the desk and ask for its immediate consideration.

The ACTING PRESIDENT pro tempore. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from South Carolina [Mr. DEMINT] proposes an amendment numbered 1018.

Mr. DEMINT. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To amend the notification provision with respect to drugs deemed to have risk evaluation and mitigation strategies)

In section 214(b)(3)(B) of the bill, insert '', except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified'' before the period at the end.

Mr. DEMINT. Mr. President, my amendment calls for the Food and Drug Administration to conduct an assessment of the risk evaluation and mitigation strategy, which we refer to as REMS, for Mifeprex, commonly known as RU–486, within 7 months of the effective date of this legislation.

According to the legislation before us, any drug that is currently on the market with restrictions on its distribution or use, which includes RU–486, would be required to have a risk evaluation and mitigation strategy. This means that RU–486 would be subject to periodic assessment of how well the risk management plan, including its restrictions, is working. Unfortunately, the bill does not establish a deadline for the risk evaluation for RU–486.

The current RU–486 abortion regimen was approved by the Food and Drug Administration in September of 2000. Since that time, the regimen has been linked to the deaths of seven women, including three Americans. The public has learned since November of 2004, through the release of documents by the FDA through a Freedom of Information Act request, that over 1,000 additional women have experienced adverse effects from the RU–486 regimen, including 9 life-threatening incidences, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection. It should be noted this dangerous drug is attacking young, healthy women.

I also want to point out the approval process for RU–486 was highly irregular in the first place. The drug regimen was approved under FDA subpart H, which is a regulation that applies to certain new drugs used for treating serious or life-threatening illnesses. While certain conditions may arise during pregnancy that are dangerous, pregnancy itself is hardly a serious or life-threatening illness.

The RU–486 regimen actually requires the use of two drugs: RU–486, which kills the child, and misoprostol,

which causes the uterus to expel the dead baby. G.D. Searle, the manufacturer of misoprostol, never sought to have its drug approved by the FDA for abortions. Nevertheless, the FDA, in what appears to be an unprecedented decision, mandated that misoprostol be used for unapproved ''off-label'' use in an abortion regimen along with RU–486.

Finally, the FDA approved the RU–486 regimen based on data submitted from clinical trials in which there was no control group comparison. This directly violates Federal law and appears to be unprecedented as well.

In my opinion, the FDA has not done enough to curb the use of this deadly drug, and for far too long the FDA has put politics ahead of science and ahead of women's health. When the Clinton administration expedited the approval process for RU–486 in the final days of its tenure, many medical professionals expressed serious concerns about the FDA's rush to bring RU–486 to market. Since then, the statistics have proven these concerns to be well-founded.

The legislation we are considering today has everything to do with drug safety. Yet we have a drug on the market that has killed several women and injured many others. My amendment simply sets a 7-month deadline for the FDA to assess the risk evaluation and mitigation strategy for RU–486. Given all the adverse events associated with this drug, this is the least we can do.

This is not an abortion issue, it is a women's health issue. Even those who support abortion agree there are serious problems with this drug. Let me read several quotes from abortion supporters which were part of a New York Times story that ran last year: ''None of these women should be dying; it's shocking,'' said Dr. Peter Bours, an abortion provider in Portland, OR, who is rethinking whether to offer pill-based or medical abortions.

Dr. Warren Hern, an abortion provider in Denver, said the latest reports demonstrated that abortions by RU–486, or Mifeprex, were far riskier than the surgical ones. ''I think surgery should be the procedure of choice,'' Dr. Hern said. ''Pills,'' he said, ''are a lousy way to perform an abortion.''

I quote again from another source: ''The complications associated with RU–486 far exceed the complications of surgical abortion,'' said Dr. Damon Stutes. He is an abortion provider in Reno, NV. He refuses to offer pill-based abortions.

Dr. Stutes, whose clinic has been bombed, said he was uneasy about agreeing with abortion proponents on anything. But the truth is the truth, he said.

Another quote:

> One needs to tell patients that the medical procedure, even though it seems more natural, may be more likely to result in death.

That is Dr. Phillip G. Stubblefield, a professor of obstetrics and gynecology at Boston University.

It is clear that even the supporters of abortion believe this drug is dangerous. It also appears that even the leader of the abortion industry—Planned Parenthood—supports actions by the FDA to further examine the safety of the drug. Dr. Vanessa Cullins, vice president for Medical Affairs at Planned Parenthood, told the San Francisco Chronicle:

> We are glad there will be continuing investigations by the FDA. We will work with the CDC, the FDA, and academicians to figure this out.

The FDA needs to quickly complete its risk evaluation on RU–486. That is what my amendment guarantees. I urge my colleagues to support it. I understand that Senator KENNEDY will accept a voice vote on this. I look forward to supporting it, along with all of my colleagues.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from North Dakota is recognized.

AMENDMENT NO. 990

Mr. DORGAN. Mr. President, I have listened to some of the debate on the floor of the Senate in opposition to the amendment I have offered with many colleagues dealing with the reimportation of prescription drugs. Especially entertaining was to hear the Senator from New Hampshire, Mr. GREGG, describe North Dakota wheatfields. The Senate is a place of fascinating and interesting debate. I expect we will have more of that in the coming hours, leading up to a vote tomorrow on a cloture motion on this amendment.

The continued and insistent reference to this amendment posing safety risks, or risks of unsafe prescription drugs, is at odds with everything we know to be the case. I described Dr. David Kessler, and I suggested if anybody knows a more important, better informed expert than Dr. David Kessler, who was head of the FDA for nearly 8 years, tell me his or her name. I described the statement that Dr. David Kessler made that says this will make the prescription drug supply safer. In fact, the regime of safety we have put into this amendment is appropriate, important, and will mean that we will be able to allow reimportation without a safety risk.

Despite the evidence, we continue to hear this issue. I was thinking, as I was listening to this a while ago, about the Lincoln-Douglas debates, when Lincoln became enormously exasperated at one point and he said to Douglas: Tell me, how many legs does a horse have?

Douglas said: Well, four, of course.

Lincoln said: Now, if you were to call the tail of a horse a leg, then how many legs would a horse have?

Douglas said: Well, five.

Lincoln said: You see, that is where you are wrong. Just because you call the tail a leg doesn't make it a leg at all.

The same principle holds true now on the floor of the Senate. You can say what you want, but that doesn't make it true. Safety issues? That doesn't exist in the amendment we are talking about. This will make the drug supply safer. While I am speaking of Lincoln and Douglas, let me say something else that Lincoln said, which has always been interesting to me. He was describing his opponent's arguments. He said: Your argument is as thin as the homeopathic soup made from boiling the shadow of a pigeon that has been starved to death.

Wasn't Abraham Lincoln wonderful? That description can still exist for some of the arguments we are hearing these days on some of these issues.

I hope my colleague was not serious a few moments ago when he said this is an amendment that is not worthy and is put out by a bunch of people who want to put out press releases and aren't concerned about the safety of the drug supply. My colleague surely doesn't mean to say that Senators GRASSLEY, MCCAIN, SNOWE, and COLLINS on his side and Senators KENNEDY, STABENOW, BROWN, and so many on our side—the 33 Senators who have come to a serious issue with a thoughtful proposal—did so because they want a press release. My colleague knows better than that. He perhaps ought to tell the Senate he knows better than that.

I respect those who disagree with this amendment. I hope they will respect as well our determination to correct something we see as a serious problem. When my colleague says we don't want to give up our lead, describing our lead in pharmaceuticals and the development of prescription drugs, I don't want to give that up. Let me tell you another lead we don't want to give up; that is, the lead in providing the highest prices in the world to the American consumer who needs prescription drugs. That is a lead we ought to relinquish right now. I wonder if my colleague would agree with that.

Mr. President, this is an interesting debate, a useful debate. It will conclude tomorrow with the vote. My colleague from Michigan, Senator STABENOW, has gone across the bridge that connects our two countries, taken busloads of senior citizens and has been involved in this issue for many years, believing that we ought to insist on fair pricing for prescription drugs for the American people. I am pleased that she was one of the people who helped put together the bill introduced by 33 Senators, and I am pleased that she is a strong advocate for the amendment that we have added to this piece of underlying legislation.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Michigan is recognized.

Ms. STABENOW. Mr. President, I rise to support the amendment we have put together, led by the Senator from North Dakota. I thank him for his passionate leadership and advocacy and the way he is able to speak in very commonsense terms about what this is all about. What we are talking about is common sense. We are talking about whether we have the most competition

that will allow the best price for people related to their medicine. I also am looking around for Senator BROWN, who is also here to speak. I thank him publicly for his help on another amendment that relates to competition and closing patent loopholes relating to generic drugs. I thank him again. Senator BROWN has been a wonderful advocate on these issues.

I find it so interesting whenever we hear that we cannot lower the price of prescription drugs without losing research. Let me comment on that first. Here is what is happening today as it relates to the development of new medicine. We all want that. We all want that, those of us who supported overwhelmingly, the 63 Members of the Senate who voted for stem cell research to provide new lifesaving research and tools for our researchers. We came together and said, yes, we want new lifesaving research.

That is not what this debate is about. The debate is about whether there is going to be a closed market to folks who get to set the price without competition or whether there will be competition so people can afford to buy medicine. The reality is that our structure is such right now, as it relates to the way we bring drugs to market, that you start with basic research, of which last year $29 billion was paid for by the American taxpayer—$29 billion. Now, the industry then added another $39 billion, according to the PhARMA Web site. They are allowed to write off their research as a business expense, or take an additional amount—the R&D tax credit on top of that to write off their research. So the taxpayers are paying, it is fair to say, the majority of what it costs in basic research right now for new lifesaving medicine.

Personally, I am willing to do that because I think it is incredibly important. It is in our public interest. Having all of us together as taxpayers invest in the National Institutes of Health and other lifesaving research makes sense to me. After we do that, we allow the companies to take that information and research and begin to develop medicine. That is fine, too. We then allow up to a 20-year patent, so that the company that does this development can recoup their costs without the same kind of competition from a generic company, another kind of company. So we give them a privileged status. We cover their costs, after we as taxpayers have helped them or may have fully funded the research done in the beginning. So we go through all this, and all that I ask on behalf of the people of Michigan and all I think we are asking for is, when they get done with the patent, people be able to afford to buy the medicine and that we have the kind of competition that allows that to happen.

One piece is to make sure patents are not extended beyond 20 years unfairly by manipulation. I will have an amendment that deals with closing some loopholes. The other is to make sure we open our borders to allow our pharmacies, our hospitals, our medical schools, all those who are providing prescription drugs to consumers, to be able to purchase those and get the best price.

In Michigan, it may be from Michigan or it may be from Ohio or Wisconsin, but it may be 5 minutes across the bridge in Canada. In fact, Mr. President, that is what we find 5 minutes across the bridge. I have had a lot of opportunities to put seniors on buses to go to a pharmacy in Canada to see the fact that you are looking at 30-, 40-, 50-percent cheaper prices. I think of my sister-in-law when I say this. She was diagnosed with breast cancer, and thank God is doing well and has recovered. But when I look at the drug Tamoxifen that many breast cancer patients are required to take, or are asked to take, in Michigan, the last time I looked, it was about $360 a month for that medicine. Five minutes across the bridge, it is $60. That is a huge difference. That is a huge difference in somebody's ability to get the treatment they need for breast cancer. That can be replayed over and over again as it relates to medicine.

Now, what is also interesting is that prescription drugs are being brought across the border every day legally by the companies themselves. Lipitor, which was developed in Michigan—and I am proud of that—is manufactured in Ireland. They bring it back. There is no argument about safety when they are bringing it back. We have, right now, around the world, from Slovakia to China to India, medications that are being brought into this country by the companies themselves, under safe conditions.

Our legislation puts into place safety requirements that will allow the same thing to happen if it is a wholesaler, a pharmacy doing business with another pharmacy. There is no rocket science here. The very same safety provisions can be put into place. We also know that, in doing that, it is important to put that language directly into this bill. It is important. We have put in there a chain-of-custody requirement to ensure that drugs are handled not only by authorized persons but shipments must use anticounterfeiting technology to assure the products' integrity.

We do a number of things that relate to registering with the FDA and agreeing to strict requirements to ensure safety. But those requirements are not all in the bill. Why is that? Because we know that in the past we have seen—we see again now—a second-degree amendment to say that citizens cannot get the best price, and pharmacies cannot do business with pharmacies across the border, unless the Secretary certifies safety. And we know that for whatever political reasons, that has not happened over the years. That is actually current law.

To get beyond the politics of this, we have worked on a bipartisan basis, with wonderful bipartisan support, to actually put the safety provisions that are required into the bill so the certification by the Secretary is not necessary.

We have had legislation passed by the Senate with wonderful bipartisan support in the last few years on related issues that involve reimportation. Last July, 68 Senators voted for an amendment to prohibit U.S. Customs and Border Protection from stopping individuals from importing FDA-approved drugs—individual reimportation.

I thank Senator VITTER for his leadership. I have been pleased to work with him on this issue of individuals being able to import medicines for themselves. Senator VITTER and I also worked together to make sure trade agreements cannot be used as a backdoor way to stop reimportation of cheaper prescription drugs into this country.

We are already on record as supporting this effort to lower prescription drug prices and create competition. It is my hope that, once again, in this bill we will reaffirm that we support the FDA creating safety regimens—we know they exist—to be able to bring medicine safely into the United States from other countries, and we will no longer allow a group—it is the only group I know that is able to stop trade at the border. Everyone talks about free and open trade, and yet in Michigan you can bring auto supplies back and forth every day, you can bring all kinds of agricultural products, you can bring anything back and forth across the border except medicine, except prescription drugs, unless you are a drug company. Drug companies can, but if you are somebody trying to make sure you get the lowest possible prices to consumers through a pharmacy, a hospital, medical school, or other businesses, you are not allowed to do it. It doesn't make any sense.

I believe we need to take off this protectionism which has been in place for years which has put consumers and businesspeople, frankly, into a situation where they are paying higher prices for medicine than they should.

This is not about research. I conclude by saying that according to SEC filings, 2½ times more is spent on marketing and advertising brand-name prescription drugs in the United States than is spent on research. This is not about research. We as taxpayers are leading the way on funding research, and we all support doing that. This is about competition versus protectionism and whether consumers will get the very best price for lifesaving medicine.

I urge the adoption of our amendment.

The ACTING PRESIDENT pro tempore. The Senator from Ohio.

AMENDMENT NO. 1018

Mr. BROWN. Mr. President, I understand there is no further debate with respect to the pending amendment No.

1018, so I ask that the amendment be agreed to and the motion to reconsider be laid upon the table.

The ACTING PRESIDENT pro tempore. Is there objection?

Mr. COBURN. Reserving the right to object.

Mr. BROWN. Mr. President, amendment No. 1018 is the DeMint amendment.

Mr. COBURN. I have no objection.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The amendment (No. 1018) was agreed to.

The ACTING PRESIDENT pro tempore. The Senator from Iowa.

Mr. LEAHY. Mr. President, will the Senator from Iowa yield to me for 1 minute?

Mr. GRASSLEY. Yes.

The ACTING PRESIDENT pro tempore. The Senator from Vermont.

(The remarks of Mr. LEAHY are printed in today's RECORD under ''Morning Business.'')

Mr. LEAHY. Mr. President, I thank my dear friend from Iowa.

The ACTING PRESIDENT pro tempore. The Senator from Iowa is recognized.

AMENDMENT NO. 990

Mr. GRASSLEY. Mr. President, I am a cosponsor of Senator DORGAN's amendment called the Pharmaceutical Market Access and Drug Safety Act. We want to add the provisions on the importation of drugs to this measure. Obviously, I support that effort. That legislation is the result of a collaborative effort by this Senator, Senator DORGAN, Senator SNOWE, and Senator KENNEDY to finally make drug importation legal in this country. This is one effort which I hope the new Democratic Congress can finally get passed because last time, my own party did not want to see this passed, even though I worked hard to get that done.

Now is the time for us to make this happen. This is a golden opportunity this year to get it done. I think we are well on the way to getting it done.

I have been a longtime proponent of drug importation. In the years 2000, 2002, and 2003, I supported amendments permitting importation of prescription drugs from one country—Canada.

In 2004, Senator KENNEDY and I worked together on a bill that would authorize drug importation, but it did not survive the partisan politics of that year.

I then introduced my own drug importation bill in 2004 with the number S. 2307. After introducing my bill, I began working in conjunction with the efforts of Senator DORGAN, Senator SNOWE, and Senator KENNEDY. So in this provision before us, we combined our efforts so that we could all get behind the same bill and have a better chance of getting it passed. Of course, that is where we are, working together this very minute.

Making it legal for Americans to import their prescription drugs is a top priority at the grassroots level, as it shows up in my 99 town meetings I have every year in each of our 99 counties, and I have been doing that for 26 years. So I think I have a feel for what the grassroots of my State wants Congress to hear.

This is one issue about which I constantly hear, although I am probably hearing it a little bit less now that we have the Part D provisions of the Medicare bill because for people who couldn't afford drugs, who maybe relied on imports or at least drugs from other countries, they are able to get them a little better through the subsidization under the Part D Program. But I still hear about this issue, and that is why I am still working to get it passed. So this needs to be a top priority in Washington as it is at the grassroots of America.

I have long advocated allowing American consumers access to safe drugs from other countries, but I have not looked at this solely or even most importantly as a health issue. I have looked at it more often as a free-trade issue. Imports of any kind coming into our country create competition and keep domestic industry of all segments of our economy more responsive to the consumer, giving the consumer what they want at a price they are willing to pay and a quality they care about.

In the United States, we seem to import anything that the consumer wants to buy in America, but we don't do it for pharmaceuticals. So why not, with this legislation, do for pharmaceuticals what we do for everything else American consumers want to buy? That is what breaking down the barriers to trade is all about. That is where our country has been for 50 years, breaking down barriers to trade around the world. Yet we keep this barrier up. Consumers in the United States then pay far more for prescription drugs than those in other countries.

If Americans could legally and safely access prescription drugs outside the United States, then drug companies would be forced to reevaluate pricing strategies. More competition would have an impact. They would no longer be able to gouge the American consumer by making them pay more than a fair share of the higher costs of research and development, which is a resource we need for research and development, but why should just the American consumers pay for that?

It is true that pharmaceutical companies do not like the idea of opening up America to the global marketplace. They want to keep the United States closed to other markets in order to charge higher prices here. However, with this amendment, prescription drug companies will be forced to be competitive and establish fair prices in America.

The drug companies will try to find, of course, loopholes to protect their bottom line, but I think our amendment is comprehensive enough to keep that action illegal. It would not allow, for instance, manufacturers to discriminate against registered exporters or importers. It would prohibit drug companies from engaging in any activities to restrict, to prohibit, or to delay the importation of a qualifying drug. The amendment would give the Federal Trade Commission the authority to prevent this kind of possible abuse of the system.

I also understand that there will be an attempt to kill this amendment, as it has been, I believe, in the years 2000, 2002, and 2003, by an amendment that would require a certification about health and safety. That amendment is designed to kill the underlying Dorgan amendment. It is a clever amendment and for sure can legitimately be determined to be a poison pill.

Our efforts develop an effective and safe system that gives Americans access to lower prices. This amendment requires that all imported drugs be approved by the Food and Drug Administration. The amendment sets a stringent set of safety requirements that must be met before Americans can import drugs from that country.

The amendment requires all exporting pharmacies and importing wholesalers to be registered with the Food and Drug Administration, as well as being inspected. It gives the authority for the FDA to inspect entire distribution chains of imported drugs, and it sets very stringent penalties for violation of the safety requirements in this bill, including criminal penalties and up to 10 years in prison.

Don't be fooled by the poison pill amendment to which I just referred. Voting for that amendment is a vote to kill drug importation.

With the Dorgan amendment, we are going to get this job done because we need to make sure Americans have even greater, more affordable access to wonder drugs by further opening the doors to competition in the global pharmaceutical industry.

I think Americans have been waiting for this for a long period of time. When a country such as ours allows every other product to come into this country that the consumer wants for the best price and the best quality, there is no reason we should make an exception for pharmaceuticals. We must make sure they have access to these affordable prescription drugs. So I urge my colleagues to support the Dorgan amendment.

Mr. COBURN. Mr. President, I want to chime in for a minute on this amendment, and I want to set a little background. Why do we want to import prescription drugs? What is the reason behind it? The reason is that there is not a true international market in pharmaceuticals. Senator STABENOW quoted a figure of $29 billion worth of Government research. That is not quite accurate. There is $29 billion that goes to NIH, but that is not all related to drug development. Probably half of that is. So we do have a great investment in drugs. There is no question

that the American consumer subsidizes the pharmaceuticals of almost every other nation in this world. So the purpose behind this amendment is a good one.

I would draw attention to the fact that Senator BROWN and I passed a drug reimportation bill in the late 1990s that became law, and President Clinton signed it. Donna Shalala, however, under the same guidelines, refused to carry out that mandate—that bill is still on the books, by the way—claiming there was nothing they could do that would make them safe and that they could assure they were safe.

I am going to vote for this amendment, and I think it is right that we should develop a worldwide market on pharmaceuticals, but I am not sure we are going to accomplish this. Having authored the first bill on drug reimportation when I was a Member in the House, what I have seen is that the problem is much bigger than what we are attacking. I find it kind of peculiar and strange that we haven't gone a little further. What really needs to happen is we need to tell all our friends around the world that tell the pharmaceutical companies what price they will pay for drugs, we need to tell them what price we will pay for their products. As soon as we did that, guess what. There would be a worldwide market on pharmaceuticals. We may get there through reimportation, but I don't think so. I think it is going to get squeezed down. I think greed conquers technological difficulty almost every time.

So I think this is a good step, but if we really want to solve this problem, let us put an amendment on the floor which says that any country that essentially fixes the price on pharmaceuticals, their products coming into our country will have their prices fixed. Can you imagine if we were to tell BMW what they are going to get for a BMW 531, or Volkswagen what they are going to get for one of their vehicles, or Toyota what they are going to sell a car for? That is essentially what they are doing to the pharmaceutical industry in this country.

I believe this is a good amendment, and I am supportive of reimportation, but I don't believe it solves the problem. I don't want the American people to think that if we pass this, all of a sudden the price of drugs is going to come down. It will not. It is great that we are doing it, but we are not going far enough. We need to ask the administration to carry out the strength of their ability through Executive orders to create true competition throughout the country and throughout the world on pharmaceutical prices.

Regardless of all the precautions and the well-thought-out plans of Senator DORGAN—and I know Senator BROWN has worked on this for years, as has Senator STABENOW and Senator VITTER and several others—I believe they will get around it. I believe they will sign contracts for fixed quantities of drugs, and then the countries that have the potential to take a drug that was produced here or produced by a manufacturer that is based out of this country, they will limit the amount of drugs that are available to them based on the contract they sign for the number of drugs. So we will have made everybody feel better, but we will not really have created a worldwide market for pharmaceuticals. That is what I think we have to do.

I would like to put out to the author of this amendment, as well as the sponsors, that we ought to think bigger on how to handle this because what we really have is one industry where there is not true free trading. We are not ever going to get the benefits, we are not ever going to relieve the burden of the American consumer, who is paying to subsidize drugs in Germany, in England, in France, and in Japan, we are not ever going to take that burden off until we really create a true worldwide market in pharmaceuticals. I am just hesitant to believe this is going to accomplish it.

Like I said, I am going to vote for it. I believe it is a step in the right direction, but I think we need to be more bold. If we really believe in the benefits of international free trade, then we should do whatever is in our power to insist it become an international market for pharmaceuticals. That way, the pharmaceutical companies won't have to use the only market there is in our country to subsidize the variable costs and the research that they contribute to a lot of the drugs that come today.

So I am supportive, I think it will pass, but I would reach out to the other Members who are interested and say: Let's do something bigger. Let's do something that will really fix it and do it fairly quickly. We will have a thriving pharmaceutical industry that way. It truly will be based on competition. Intellectual properties that are truly researched and supported by the country—we as Americans, if we have done that, we will get the better benefit from it if we have a true international market. I think the drug companies would like to see that as well.

I understand they are trying to get return on invested assets. I believe it is important that everyone has a fair price for a pharmaceutical and that people make money when they sell a pharmaceutical. But we have to have an international market, and we have to solve it that way.

I thank Senator BROWN for allowing me the time, and I yield the floor.

AMENDMENT NO. 985

Mr. BROWN. Mr. President, I thank Senator COBURN for his always innovative approach and his support of this and for all he does in working on health care issues generally and especially on prescription drugs.

Mr. President, I ask unanimous consent that the pending amendment be set aside, and on behalf of Senator BROWNBACK and myself, I call up amendment No. 985.

The ACTING PRESIDENT pro tempore. Is there objection?

Hearing no objection, it is so ordered.

The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Ohio [Mr. BROWN], for himself and Mr. BROWNBACK, proposes an amendment numbered 985.

Mr. BROWN. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To establish a priority drug review process to encourage treatments of tropical diseases)

At the appropriate place, insert the following:

SEC. ___. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

''(a) DEFINITIONS.—In this section:

''(1) AIDS.—The term 'AIDS' means the acquired immune deficiency syndrome.

''(2) AIDS DRUG.—The term 'AIDS drug' means a drug indicated for treating HIV.

''(3) HIV.—The term 'HIV' means the human immunodeficiency virus, the pathogen that causes AIDS.

''(4) NEGLECTED OR TROPICAL DISEASE.—The term 'neglected or tropical disease' means—

''(A) HIV, malaria, tuberculosis, and related diseases; or

''(B) any other infectious disease that disproportionately affects poor and marginalized populations, including those diseases targeted by the Special Programme for Research and Training in Tropical Diseases cosponsored by the United Nations Development Program, UNICEF, the World Bank, and the World Health Organization.

''(5) PRIORITY REVIEW.—The term 'priority review', with respect to a new drug application described in paragraph (6), means review and action by the Secretary on such application not later than 180 days after receipt by the Secretary of such application, pursuant to the Manual of Policies and Procedures of the Food and Drug Administration.

''(6) PRIORITY REVIEW VOUCHER.—The term 'priority review voucher' means a voucher issued by the Secretary to the sponsor of a tropical disease product that entitles such sponsor, or a person described under subsection (b)(2), to priority review of a new drug application submitted under section 505(b)(1) after the date of approval of the tropical disease product.

''(7) TROPICAL DISEASE PRODUCT.—The term 'tropical disease product' means a product that—

''(A) is a new drug, antibiotic drug, biological product, vaccine, device, diagnostic, or other tool for treatment of a neglected or tropical disease; and

''(B) is approved by the Secretary for use in the treatment of a neglected or tropical disease.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product upon approval by the Secretary of such tropical disease product.

''(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may

transfer (including by sale) the entitlement to such voucher to a sponsor of a new drug for which an application under section 505(b)(1) will be submitted after the date of the approval of the tropical disease product.

''(3) LIMITATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product was approved by the Secretary prior to the date of enactment of this section.

''(c) PRIORITY REVIEW USER FEE.—

''(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a drug that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the anticipated costs to the Secretary of implementing this section.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

''(4) PAYMENT.—

''(A) IN GENERAL.—The fee required by this subsection shall be due upon the filing of the new drug application under section 505(b)(1) for which the voucher is used.

''(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection is not included in such application.''.

Mr. BROWN. Mr. President, I rise today to offer the Brownback-Brown amendment, No. 985, which provides incentives for pharmaceutical companies to develop and manufacture treatments for neglected tropical diseases. According to the World Health Organization, more than 1 billion people—that is one of every six people worldwide—are affected by at least one neglected tropical disease. In addition, neglected tropical diseases claim roughly 500,000 lives every year. However, less than 1 percent of the roughly 1,400 drugs registered between 1975 and 1999 treated such diseases.

This disparity is obviously due to the lack of financial incentives for pharmaceutical companies to bring neglected tropical disease treatments to market because these diseases disproportionately affect low-income countries, mainly in Africa. Creating incentives for companies to invest in treatments for these diseases is not only in our country's national interest, but it is consistent with the longstanding tradition of this country of caring for those less fortunate around the world.

This amendment would award a priority review voucher to any company that brings a neglected tropical disease treatment to market. Priority review is an existing FDA process by which drugs are reviewed in 6 months as opposed to the average time of 18 months. This priority review voucher would be transferable and could be applied to any drug in a company's pipeline.

This voucher, which would be worth hundreds of millions of dollars for a company with a new blockbuster drug, would also benefit consumers. That is because it would give consumers earlier access to a new prescription drug. Most importantly, creating incentives for pharmaceutical companies to develop and manufacture neglected tropical disease treatments will obviously save lives.

I commend Senator BROWNBACK for his hard work on behalf of impoverished populations who desperately need our attention. He is offering Members of this body the opportunity to simultaneously save lives in developing nations, get U.S. consumers access to new medicines more quickly, and engage the drug industry in a win-win proposition. It is a rare opportunity, and I urge Members on both sides of the aisle to support the Brownback-Brown amendment.

AMENDMENT NO. 1011

Mr. President, I would like to make a few comments on two other amendments, the first being the Stabenow amendment, which I have also cosponsored, along with Senators LOTT and THUNE. That amendment will save U.S. taxpayers hundreds of millions of dollars while restoring the integrity of the citizen petition process. That is important because the citizen petition process is fundamental to our Nation's democratic system.

Under U.S. law, individuals and organizations have the right and should have the right to petition the Federal Government, which is another way of saying they have a right to communicate their views and have their views heard. The Federal Government is, after all, an employee of the American people. Americans absolutely should have the right to weigh in on Government policies and actions.

Unfortunately, some brand-name pharmaceutical companies have regularly exploited the citizen petition process, filing frivolous petitions solely for the purpose of delaying the approval of generic drugs. They have been quite successful at it. Since 2003, brand drug companies have filed dozens and dozens of citizen petitions trying to stop or delay FDA approval of competing generic products. Ninety-five percent—roughly 19 in 20—of these petitions have been denied outright. What about the other 5 percent? FDA either hasn't acted on them or has approved them in whole or in part because they had no other choice—the brand companies had simply reiterated a factual issue that had already been addressed by FDA. In other words, even the approved petitions, the approved 5 percent, were frivolous.

While drugmakers waste FDA's time and taxpayers' money, American patients are forced to continue paying top dollar—the name-brand price—for the medicines they need. Frivolous citizen petitions have created delays that often range from 11 to 15 months, preventing price competition for drugs that generate millions of dollars in revenue each day. American consumers—American taxpayers, who help finance Medicare, Medicaid, and VA health care—can't afford it. These costs are borne not just by consumers and taxpayers but also employers.

I have worked closely with Senator STABENOW to make sure this amendment doesn't interfere with the right of individuals or companies to petition FDA and that the amendment ensures these individuals that the concerns raised in their petitions will still be taken seriously by FDA. What this amendment does do is fight back against the unjustifiable and costly delays caused by frivolous petitions submitted for the express purpose of blocking price competition in the marketplace.

No one, not the drug industry or any other industry, should be allowed to make a mockery of one of our democratic rights—the right to petition our Government—particularly at the expense of patients and taxpayers. Ms. STABENOW's amendment, cosponsored by Senator THUNE and Senator LOTT, will put a stop to a tactic which is as costly as it is unethical. I urge every Member of this body to support it.

AMENDMENT NO. 990

Mr. President, I also would briefly speak out on the Dorgan reimportation amendment, joining Senators GRASSLEY and STABENOW and so many others in both parties in supporting the reimportation amendment.

Some time ago, about 10 years ago, from my northeast Ohio congressional district when I served in the House of Representatives, along with the Presiding Officer, I used to sponsor bus trips to Canada where we would take mostly senior citizens to a Canadian drugstore right across the river from Detroit—Windsor—which was about a 3- or 4-hour bus drive from Lorain County, where I lived. We would take a busload of 40 seniors and others—mostly seniors, as I said. We would buy prescription drugs in Canada—same dosage, same package, same drug manufacturer, for half or even sometimes a third the cost because the Canadian Government directly negotiated on behalf of 30 million Canadians, negotiated directly with the drug company for specifically less expensive drugs. It was clear to me then that reimportation was legislation we needed so seniors did not have to go to Canada; instead, that wholesalers, the Drug Marts and the CVS's of the world and the mom-and-pop drugstores can negotiate, could get those prices wholesale from Canadian drugmakers or companies and bring those prices significantly down for American consumers.

As Senator COBURN said, when we were House Members we passed legislation 8 or 9 years ago. That legislation was never implemented the way it should have been. The Dorgan amendment will save money for America's seniors, for America's drug consumers, for prescription drug users. It is an important amendment, and I ask for support for the Stabenow amendment, the

Dorgan amendment, and the Brownback-Brown amendment.

I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The bill clerk proceeded to call the roll.

Mr. CASEY. Mr. President, I ask unanimous consent the order for the quorum call be rescinded.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The Senator from Pennsylvania is recognized.

Mr. CASEY. Mr. President, I stand today in support of an amendment to S. 1082 offered by Senator DORGAN and several of our colleagues. This amendment is identical to a bill sponsored by the Senator from North Dakota, a bill I am proud to cosponsor.

We have a serious problem today with drug prices all across our land. The American people have asked us to do something constructive about this crisis. Why is it Americans pay the world's highest prices for prescription drugs? This is simply not fair, and I have to believe we can do better in America. While the issues contributing to prescription drug prices are many and complex, this amendment, the Pharmaceutical Market Access and Drug Safety Act, offers a genuine and workable piece of the solution.

It is no secret to anyone that Americans already import many prescription drugs, and I have heard from constituents in my home State of Pennsylvania about buying drugs outside of this country. A recent study shows that would cost from 35 to 55 percent less than constituents of mine are paying. They can pay a much lower price if they are able to get prescriptions from another country. Seniors who are living on limited incomes are especially vulnerable and need to cut costs wherever they can.

We all know the high cost of health care across all of our States is prohibitive for so many vulnerable citizens—children, working families, and older citizens. The reality is when the monthly budget has been spent on necessities such as food or childcare, doctors' visits, housing, transportation—when all those costs are incurred, many families do not have money left over for medicine. These individuals may have no choice but to forgo needed medicine and hope for the best.

Another recent study found 43 percent of uninsured Americans ages 19 to 64, and even 18 percent of insured adults, did not fill a prescription because of cost. This is in the richest country in the world. We can do a lot better than that, and we must do better than that.

I support this legislation because it gives us the opportunity to help families in America, and to do so safely. There are a number of safety features that are intended to guarantee that only safe and effective—let me say that again, only safe and effective—FDA-approved drugs are imported across our borders. These safety features are comprehensive. For purposes of time, I want to highlight a few.

First, this act allows only the importation of FDA-approved medicines with a chain of custody, to ensure that drugs are handled only by authorized persons. In most cases, the medicines that are imported under this act are identical to the medications sold in the United States—literally the same medications made by the same manufacturers.

Exporters would be required to maintain detailed records and a sample of each lot sent to the U.S., so that the FDA can conduct testing on any lot at any time. The FDA would have broad authorities, including the power to cease importation of a drug or to suspend a registered exporter without notice. The FDA also has the authority to inspect all facilities in the chain of custody of a drug.

The bottom line is this bill gives the FDA broad authority and the resources to ensure that imported drugs are in fact safe. It is unacceptable that working parents have to make a choice between medicine they cannot afford for their child and making the rent payment on time. It is unacceptable that older citizens have to choose between paying for needed medication and paying for food.

This Chamber can do something about this challenge, can do something about this Hobson's choice so many families face every day in America. The Dorgan amendment provides an effective regulatory framework to ensure that imported drugs are safe for our families. I urge all my colleagues to support this amendment which will provide an invaluable piece of the solution to making FDA-approved prescription drugs affordable for everyone.

The PRESIDING OFFICER. The Senator from Oklahoma is recognized.

Mr. INHOFE. Mr. President, I ask unanimous consent that I be permitted to speak as in morning business for up to 10 minutes.

The PRESIDING OFFICER (Mr. BROWN). Without objection, it is so ordered.

(The remarks of Mr. INHOFE are printed in today's RECORD under ''Morning Business.'')

Mr. INHOFE. Mr. President, I yield the floor, and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

The PRESIDING OFFICER (Mr. WHITEHOUSE.) The senior Senator from Maine is recognized.

Ms. SNOWE. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Ms. SNOWE. Mr. President, I rise in support of the amendment that has been introduced by Senator DORGAN with whom I have joined as a cosponsor regarding drug importation.

First of all, I commend Senator DORGAN for his longstanding leadership and advocacy on this issue which has been for the better part of a decade. Regretfully, we are still at a point where we have been unable to pass legislation that would create a drug safety regime for drug importation.

That is the purpose of our amendment, Members of the Senate, as we today consider legislation to address an essential new function in how the FDA will finance the cost of reviewing new drugs; that is, the critical process of bringing new medications to market to Americans.

At the same time, this bill has directly raised a number of issues in how we assure that drugs are as safe as they should be, how we can bring new low-cost generic biologics to market. Key to this debate on this legislation that is pending before the Senate is the adage, which we have heard time and time again, that is: A drug which is not affordable is neither safe nor effective.

The simple fact is, even with the new Part D prescription drug benefit as part of the Medicare Program that has been in place for more than 2 years now, we still have at least 60 million Americans overall that today pay the full price of medications, have no help whatsoever because many have no health insurance or their insurance does not provide coverage for prescription drugs.

At the same time, the price that Americans are paying is the highest price in the world. For those of us who are fortunate to have prescription drug coverage, the estimated cost of medications is part of the major exorbitant increase in the cost of health care.

Many of my colleagues have recognized that our system lacks competition that would assure our constituents more affordable access to lifesaving medications. That is why I am very pleased to join with the Senator from North Dakota, and we have the support of a bipartisan group of colleagues in the Senate, along with Senators GRASSLEY and KENNEDY and Senators MCCAIN and STABENOW who are unified with us in supporting this bipartisan approach.

Today, our voices echo those of 8 out of 10 Americans who are calling for safe importation. After nearly 3 years of awaiting Senate consideration of our legislation in 11 related hearings on this subject in the Senate, we simply must move forward. The reason is abundantly clear. We know the cost of health care is rapidly rising in America.

Prescription drug prices have contributed to that exorbitant increase. Compared to 1990, nearly twice as much of our health care dollar goes to medications. As the GAO has readily told us, the cost of prescription drugs commonly used by seniors has consistently increased at two to three times the rate of inflation, as indicated by this

chart, when you are comparing brand drugs, generics, and the CPI.

That is why we can no longer afford to postpone any action. We have acted before. We acted on legislation back in 2000. Then we also took action with respect to the Medicare Modernization Act in 2003 which created a Part D prescription drug program. We have found the requirements for the Secretary of Health and Human Services to certify the safety and savings of drug importation have blocked any action; it has become a roadblock to safe importation.

While FDA was unable to point to a single individual harmed by Canadian drugs—and in Europe, where they have had a track record of more than 30 years of parallel trading—it has proven that this trade can be conducted safely.

Time and time again, they have demonstrated that their process of parallel trading has worked without any harm to their consumers. Without a doubt, Americans would not be turning to imports if there was not substantial savings. Indeed, the CBO has told us that countries from which we would import under this bill would pay 35 to 55 percent less for a brand prescription drug. Let me repeat that—35 to 55 percent less than we pay today.

In other words, American consumers are paying 35 to 55 percent more than foreign consumers when it comes to medications. That is remarkable. We have seen so many objections to this legislation for the better part of a decade. That is why we have taken it upon ourselves to develop a regime that has been incorporated in this amendment and in our legislation that would address every facet, every issue that is associated with safety in order to allow drug importation to occur.

As I said earlier, the European Union has already engaged in parallel trading for three decades without incident. As seen here on this chart, where we have incorporated 31 different key safety provisions in our legislation, and compare that to the Medicare Modernization Act that passed in 2003 that created the Part D prescription drug benefit to the Medicare Program, only 6 provisions that related to safety were incorporated in that landmark initiative.

We include 31 different initiatives to address every single safety-related issue that has emerged in this debate. Whether it has been on the floor of the Senate, whether it has been in the course of hearings or elsewhere, we have addressed every safety-related issue to create a regime that should create the assurance that this can be done safely and without harm to Americans so they can benefit from lower priced medications.

Americans deserve to have the lower priced medications. The FDA can conduct this program. They can conduct this regime. They should work proactively to assure these drugs are safe. We give them the means and the wherewithal and the resources in order to accomplish this. We comprehensively address the various concerns that have been raised months and years about drug importation so we can get something done.

People say: Well, let's just certify safety. Well, as I have said earlier, it is a roadblock. It is an impediment to get anything done. It essentially becomes the poison pill. We have tried certification. We have given the Secretary of Health and Human Services under two administrations—this administration and the previous administration—the ability to do that, to certify it. They are unwilling to do so because they have said they do not have the resources, they do not have the means.

Well, we are giving them the means and the resources. But to pass another amendment that simply calls for the Secretary of Health and Human Services to certify drug importation is a roadblock. It is a road to nowhere with respect to this initiative. That is why Senator DORGAN and I took a different route.

We address all the safety questions. We do not certify to ensure safety, we take action with these provisions. What we do is employ the measures to actually make drug importation safe.

Opponents claim importation will cause harm. But they fail to note that the greatest threat to the safety of Americans is the inability to take a drug as it is prescribed. That exacts a toll on thousands, if not millions, of Americans each and every year, not to mention lives lost.

Some say Americans would receive drugs from illegitimate sources, but under our legislation, Americans will receive imported drugs from 32 countries with high standards. In most cases Americans will purchase an imported prescription drug from their local pharmacies just as they do today. The pharmacies will receive these drugs from the U.S. wholesalers which import them. These wholesalers will have been registered. They will be inspected. They will be monitored by the FDA. This higher level of safety is also a first step in establishing a higher standard for handling of prescription drugs right here in the United States where we have had the preponderance of problems.

Our legislation allows individuals to directly order medications using an FDA-registered and approved Canadian pharmacy. Again, just as with wholesalers handling prescription drugs, the FDA will examine, register, and inspect these facilities on a frequent basis. The FDA will assure the highest standards for such functions as making sure the medical history is recorded of the individual, verifying prescriptions, and tracking the shipments.

Some say consumers will get medications they should not be getting. Regardless of whether one purchases imported drugs from the local pharmacist or uses a Canadian pharmacy, we assure that a legitimate prescription and a qualified pharmacist will be vital ingredients to ensuring safety. In fact, we have many standards incorporated in this legislation in which it would occur.

We adopted language that had been introduced by the Senator from California, Mrs. FEINSTEIN, with respect to Web sites and domestic Internet pharmacies so that we assure that properly licensed pharmacies and pharmacists are behind Web sites that are offering these medications.

Some say importation will allow unapproved drugs to enter the United States. Again, on that point, our legislation is abundantly clear. Every drug received will always be FDA-approved. If any difference exists in a foreign drug, even the most minute, our legislation assures FDA will evaluate the product and determine its acceptability. If the drug is not bioequivalent to a U.S. drug, the Secretary may reject approval of that medication.

Some say we will import counterfeits. The truth is, today the FDA does not know even the level of domestic counterfeiting where, as I said earlier, the preponderance of the problem exists. It is simply not employing the very anticounterfeiting technologies which our legislation demands in order to ensure that we protect against the threat of counterfeits. The fact is, we employ technologies today like the ones we use now for twenty-dollar bills. We can use the same for prescription drugs.

Moreover, this bill supports development of future anticounterfeiting and track-and-trace technologies, very effective methods which we hope will be used to protect all drugs. For those who say consumers would not know who has handled the imported prescription drug, again, our bill requires a chain of custody, a pedigree to be maintained and inspected to help ensure the integrity of imported medications. A pedigree for prescription drugs was mandated, believe it or not, by law in 1988 and still has not been implemented by the FDA. Under our legislation, at last we will require pedigrees to be implemented for all medications.

Some opponents will even attempt to alarm Americans about the countries from which we import drugs, citing Latvia, Estonia, Slovakia, and members of the European Union. But consider that another member is Ireland where Lipitor is made. Again, I call your attention to this chart which indicates the European Union and other countries from which we import drugs designated in blue. They either meet our standards or have even higher ones, ones as you can see in this chart, all of the blue countries from which we would import. They have our standards or they exceed our standards.

In contrast, this chart denotes the countries in red from which, again, our manufacturers import medications. That is interesting. The FDA inspects pharmaceutical manufacturing plants in these countries denoted in red. These are countries from which manufacturers will import products. It includes China, India, Bulgaria, Jordan,

and other countries. In fact, they have lower standards. So what I have indicated, based on what this map shows, is that we have the blue countries from which we would allow importation of drugs that would be FDA-approved, facilities inspected, documented. We would have pedigrees and technologies to track the shipments. These are countries that meet or exceed our standards. Today we already have FDA pharmaceutical manufacturing plants in these countries in red that, in fact, have lower standards. So we already, amazingly enough, allow medications to come in from countries that have lower standards. Why do we? Because they are inspected by FDA. So the same process can't work for countries that meet or exceed our standards already, that already have a track record in parallel trading in and amongst their own countries, and we can't do it today for those countries when FDA already does it for other countries that have lower standards? Because that is where many of our medications are manufactured. That is where our manufacturers import and FDA inspects those facilities before those medications enter the United States. So this is already done. It is done with countries that have lower standards, and we find that acceptable. Yet we say we are not finding it acceptable from countries that already have a track record of parallel trading amongst their own country without injury to any of their consumers over the last 30 years that meet or exceed our standards. It simply doesn't make sense.

We are setting a model for improving safety because we are saying we are going to create 36 different measures for establishing safety for the American consumer to assure all those concerned that we have the measures in place and the resources with which to do it. So to those who say importation is unsafe, we show them how it shall be safe under our legislation. It sets a model and a standard.

Some say consumers will not see significant savings. But drugs imported under this program will be labeled as imports so consumers will have the opportunity to do some comparative shopping. They will be able to take those prices and do a side-by-side comparison between the imports and those medications they buy in the United States. Consumers have become well aware of foreign pricing and the competition that exists between imported and wholesalers. We know they will achieve consumer savings; there is no question. That is why so many Americans, including many of my constituents from the State of Maine who have been able to access medications from Canada, have had to take bus trip after bus trip. They have been compelled to do that in order to achieve savings because of our unwillingness to address this issue in the Senate and the overall Congress. This legislation should have been accomplished a long time ago.

In terms of savings, it should be interesting to note the independent analysis of the Congressional Budget Office which has confirmed that the savings, indeed, should be substantial—not surprising. It would be very substantial, indeed. They estimate a 10-year direct savings alone of $50 billion to the American consumer—$50 billion. That is probably on the conservative side. The Federal Government stands to save $6.1 billion in the Medicare and Medicaid Programs alone. This is only the savings that CBO projected from purchases of imports. With increased competition in our markets, we could indeed save more, having competition, having the pharmaceutical industry have some competition in their pricing. Understand, individuals can't import medications. Pharmacists can't import medications. Only manufacturers can. So we are saying: Let's set a standard. Let's allow imports that benefit the individual consumer with safety-related provisions put in place.

In fact, in a recent Commerce Committee subcommittee hearing, we had the opportunity to hear from a number of experts. We heard from a pharmaceutical economist who estimated that importation could result in a 12- to 20-percent reduction in domestic drug costs. That is an annual savings, not over 10 years, of up to $40 billion per year, as competition is created for consumer savings. So as a direct result of the competition that would develop as a result of importation, consumers alone could save up to $40 billion a year.

So at a time when health care spending is reaching 16 percent of GDP and is climbing, this competition is an imperative. It is central. It is central to the consumer who is facing double-digit increases in prescription drugs. Prescription drugs are not getting cheaper in America. They are getting more expensive. As I said, the American consumer is spending 35 to 55 percent more than the foreign consumer. Health care spending is 16 percent of the GDP. Much of the increase in health care spending is attributed to the rising cost in prescription drugs.

So that is why this becomes all the more important to the American consumer and, indeed, to the Federal Government that will save $50 billion over 10 years and 6 billion alone in Medicare and Medicaid spending. That is important to our own interests and to our budgetary concerns about the growth in these respective programs.

Some have argued that we haven't provided the resources necessary to run an importation program. But we have established a means of financing, a small fee based on the value of imported drugs which will now be set at a cap of 2.5 percent. We have always agreed that the FDA should have adequate resources. In fact, we heard from previous Secretaries of Health and Human Services, we don't have the resources to certify safety. So now we are providing a certification for that by including this cap of 2.5 percent for a fee on the total import of medications. This is what CBO has indicated to us would be necessary in order to accomplish and implement these safety-related measures. We think it is important the FDA have the resources that are essential for regulation, for monitoring inspections of both domestic wholesalers, who would import the prescription drugs, as well as the Canadian pharmacies from which American consumers could order.

Some say our bill is intended to adopt Canadian prices. Again, quite the contrary. We open importation to 32 countries which meet our safety standards. We are not simply adopting the price of another country. Rather, we are purchasing in a world market. That is a critical point. We are allowing American consumers to benefit from worldwide prices because of the competition that would be allowed. Obviously, something is happening in other countries where we want to import these medications because they are paying 35 to 55 percent less than American consumers. Why should that be the case? These are countries, by the way, that meet or exceed our standards when it comes to drug safety. Yet American consumers are paying 35 to 55 percent more for the same medications.

Some say we compel manufacturers to sell the product. But our bill is very clear on that specific point. We never compel any manufacturer to sell any particular product. But when a manufacturer chooses to sell product, the bipartisan bill prohibits discriminatory acts against pharmacists and wholesalers who sell these medications. Those actions have reduced supplies of essential drugs for some Americans, at peril to their health.

We are saying they cannot take action that discriminates against a pharmacy because they have sold those drugs to an American consumer. They are not penalized because their supplies are cut off by the manufacturer as a means of punishment and discrimination.

Now, some say importation will threaten research and development. But the fact is, manufacturers will invest just as other industries do, in order to develop innovative products and remain competitive. The taxpayer is a partner in that investment. The American taxpayer is a partner. The taxpayer makes investments in research and development. In fact, we fund nearly $30 billion a year to do basic and applied research at the National Institutes of Health alone—$30 billion.

So as you can see on this chart, as to R&D spending from all the companies, we—the United States consumer and taxpayer—fund and underwrite much of their research and development.

As I said earlier, other industrialized countries pay 35 to 55 percent less for their drugs. But because of the higher prices Americans pay for their medications, the American consumer ends up

paying $99 billion more for their prescription drugs each year than otherwise would be the case. Let me repeat that. Because we pay 35 to 55 percent more than foreign consumers, American consumers end up paying $99 billion more for their medications.

With all that additional profit, the industry spends about $9 billion more on research and development than they do in Europe. That is 10 cents return on the dollar for all that added profit margin. So while the American consumers spend $99 billion more for their prescription drugs than foreign consumers, in Europe, for example, American pharmaceuticals spend only $9 billion more—from that $99 billion—on research and development than they do in Europe. We spend only $9 billion more here than they do in Europe on research and development. That means American pharmaceuticals are netting $90 billion more, that they are only investing $9 billion more in research and development.

So it is not undercutting their ability for research and development, not to also mention, by the way, the American taxpayer invests more than $30 billion at the National Institutes of Health alone for basic research as well.

In fact, if you look at the R&D spending of the largest pharmaceutical firms—as indicated again by this chart—it is not markedly different from many other firms. If you look at other firms, such as Intel, Microsoft, Lucent, and others with high research and development costs and relatively low production costs, their research and development spending averages about 14.3 percent of gross revenues—not much different—yet their products are highly competitive, very competitive. You have seen the software, cell phones, computers, laptops, whatever. You have seen the very competitive pricing today, yet they make an investment of 14.3 percent for research and development as a percentage of their gross revenues.

Yet, paying the world's highest prices for drugs does not ensure additional research, but it certainly does decrease access to drugs. So while they do not invest in considerably more research and development—since we pay $99 billion more in prices for prescription medications, and they only spend $9 billion more on research and development, and the taxpayer spends $30 billion at NIH alone, as I indicated; but even, comparatively speaking, it is 14.4 percent of their gross revenues that are invested in research and development—if you compare that to, as I said, Intel, Microsoft, Lucent, and other companies, which is 14.3 percent, you find more competitive products in the technology arena. Their prices are coming down. The American consumer is not benefiting from the investments that are being made by the pharmaceuticals, yet it is a highly profitable industry. So we are not seeing the same benefits that would yield lower prices for the American consumer.

Now, in conclusion, let me say, I hope this Senate will adopt this amendment that creates the kind of safety regime that would ensure drug importation will become a reality. Simply certifying safety on the part of the Secretary of Health and Human Services has been tried and yet has never accomplished that goal. It has been an impediment to drug importation. It has occurred twice in the last 10 years, and for whatever reasons the Secretaries in the previous administration and this administration have concluded they will not certify the safety regime because there has been no safety regime. It could be done, but it has not been done through the agencies. FDA could do it. It has not accomplished it. It has not implemented it. It has not had the impetus to pursue it. That is why we have taken it a step further. This legislation has been examined, reexamined, based on the concerns that have been expressed by those who have been opposed to it in the past saying they have concern about safety.

We understand that. So we have gone a step further and incorporated every safety-related measure possible that is achievable, measurable, and provide the FDA with the resources to accomplish it.

The Senate has voiced its view to provide market access on this issue on many occasions, even by virtue of passing the certification standard. Obviously, I think there has been an indication on the part of the Senate to support some type of initiative that allows for drug importation. But we want to mitigate the concerns that have been expressed repeatedly about the issues of safety by incorporating all of those measures in this amendment that is pending before the Senate.

In fact, 68 Members of this body voted to adopt the amendment that was offered by the Senator from Louisiana, Mr. VITTER, to the Homeland Security appropriations bill. But we need more than to simply allow importation. We must provide an effective framework that will address the concerns that will ultimately ensure the safety of our consumers.

Sixty-eight Members of this body supported blocking the Customs agency from banning drug importation, so it is obvious Members of this Senate truly want to pass a measure that will allow for drug importation. That is why I think this legislation logically affords us the ability to provide the safety and, at the same time, allow consumers in America to benefit from competition, from lower prices, based on the track record and the experience of other countries that have been adopting this approach for many decades.

Competition is what is missing in this process. It will work for the consumer. To date, the process has not worked for the consumer where they have benefited from lower prices for medications because there has been no competition. Competition has been virtually absent. I note the comment of the former Pfizer CEO, Hank McKinnell, who wrote:

> Competition is good medicine for economies. . . . Name an industry in which competition is allowed to flourish—computers, telecommunications, small package shipping, retailing, entertainment—and I'll show you lower prices, higher quality, more innovation, and better customer service. There's nary an exception. Okay, there's one. So far the healthcare industry seems immune to the discipline of competition.

Those are the words of the former Pfizer CEO, Hank McKinnell.

It is indeed time to make competition work to benefit consumers and taxpayers. Americans deserve and will seek out affordable life-sustaining medications. We must assure that access is safe. That is what we accomplish in this amendment that is pending before the Senate.

Again, I thank my colleague from North Dakota, Senator DORGAN, for his leadership on this question and for all those who are supporting this initiative.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senate majority whip.

AMENDMENT NO. 1022

(Purpose: To ensure the safety of human and pet food.)

Mr. DURBIN. Mr. President, in a brief period of time I will be offering an amendment which I hope to bring to a vote very shortly, perhaps in the next 15 or 20 minutes, depending on the wishes of the chairman of the committee and the ranking member, Senator ENZI.

This amendment relates to the issue of food safety. This has been one of my concerns for a long time as a Member of the House and the Senate. I know everyone across America trusts that the food they buy for their families and everyone in their house is safe, that they can eat it and not get sick.

We all know what has happened over the last several months. Whether we are talking about contaminated E. coli in spinach, salmonella in peanut butter, or the latest pet food contamination, people are asking questions of Members of Congress and this Government: Are we doing our job? What is happening here? Why are so many dangerous food products showing up so frequently? How can we protect ourselves?

For many years I have thought the real answer is to tackle the whole issue. I have said it before on the floor, 12 to 15 different Federal agencies inspect our food—imagine that—and they all have different standards. Some inspect food every single day. Go to a meatpacking plant, poultry processing plant; the food is inspected every single day, every minute of every day, as it passes along those lines by the U.S. Department of Agriculture.

Fish is another story. Fish is inspected by the Food and Drug Administration. How do they inspect it? By

what they call the ''sniff test.'' They lean over and smell the fish, and if they have what they call a ''head snap,'' they know they have a bad load of fish. Sounds kind of comical, but it is what we get down to, by and large, in terms of inspecting fish.

So when you go throughout our Government and look at different products and how they are inspected, it makes no sense why different agencies are doing different parts of the food chain. From a consumer's point of view, I do not want to know there are 12 or 15 different agencies at work, with their lights on, in Washington, with a lot of different employees. I want to know there is one good agency, scientifically driven, that is making the right call as to whether there should be an inspection every day, every month, every year—whenever.

They do not have that today, and the system breaks down. What we have seen happen over the last several months is a clear indication that our food safety system—as good as it may be—needs to be a lot better. So I am offering this amendment on food safety.

I thank the Senator from Wyoming who has been very cooperative and helpful in making certain this is a bipartisan amendment. There is nothing partisan about food safety. We should all agree that the goal is one both parties share, all Americans share. Senator KENNEDY has given me the time to offer this amendment on this important bill early on, and I certainly appreciate it. Senator ALLARD from Colorado, a veterinarian, has been involved in this negotiation, as has Senator HARKIN, the chairman of the Agriculture Committee. Many people have come together to take a look at this and make sure it is moving in the right direction.

There was an early warning. The early warning came a few weeks ago when we had a pet food crisis. People who own dogs and cats know what I am talking about. All of a sudden there was a suspicion that the food you were giving your dog—that animal you love, an animal that is part of your family—could be poisoning that animal. Well, for 90 million Americans that is a big deal, and they were concerned about it. So we started looking into why this pet food was contaminated.

That crisis was an early warning signal to America. It was a warning signal that we came to learn had a lot to do with the imports coming into America. More and more imports of food products are coming in from overseas. If you believe we have inspectors sitting in China and France and Germany and Brazil taking a look at these things as they come off the assembly line, taking a little test sample and running it to the lab, you are wrong. It does not happen. In fact, once the shipment is on the boat, or on the plane, coming to America, the odds are 99 to 1 no inspector will ever look at it before it is put into a food product—99 to 1. Only 1 to 1.5 percent of food products sent to America is actually inspected by our Government.

Now, we look at what came over from the Chinese and find out they were adding a chemical to wheat gluten, a protein product called melamine. Melamine is a chemical derived from coal, which is used in the manufacturing of plastic. It has no business in anything that is edible. It was put into the shipment of protein, this wheat gluten, in order to enhance its value because when they tested this wheat gluten on its arrival, this melamine chemical indicated the presence of nitrogen, therefore, more protein, and, therefore, it was worth more. They would sprinkle in the melamine and make more money off the shipment. If this were the end of the story, you would say: Well, that was a pretty nice move; they just made a bigger profit off the shipment. It wasn't the end of the story. It turns out that wheat gluten, when used for pet foods, is toxic. Over 4,000 animals died across America because of melamine and possibly other contaminants. We are still investigating.

So we went to find out how it got into the shipment, and the Chinese did not cooperate. They have started to. I am glad they have. They have agreed to visas for our inspectors. But this pet food crisis was a warning sign, a signal to us in America that this dramatic increase in imports of food products leaves us vulnerable. Today, it was your cat or your dog. Tomorrow, it could be someone in your family whom you love. So we address part of this in this bill.

Secondly, it is an indication that the Food and Drug Administration doesn't have the authority or the resources to do their job as well as they should. This is a great agency. They have an awesome responsibility. We heap more and more responsibility on them each year, we provide them very little by way of additional resources, and they are being stretched to the absolute limit. Of course, this pet food crisis is an early warning that the whole food safety system has to be investigated and honestly looked at. So this is a start. It is an effort to try to make a difference.

I wish to thank Senator KOHL from Wisconsin and Senator BENNETT from Utah. When the pet food crisis came out, they called a timely hearing after our Easter recess, and we started working on this amendment just at that moment, and thanks to them for realizing the importance of this issue.

I also thank those who helped us draft this legislation—the Center for Science and the Public Interest, the Humane Society, which has been terrific from start to finish, the American Veterinary Medical Association, and the Coalition for a Stronger FDA.

Special thanks, while I am giving out bouquets here, to my staffer David Lazarus. This young staffer has really put his heart and soul into this effort. It is his first major legislative undertaking, and I commend him for the very fine job he has done.

Let me say very briefly what this amendment will do. First, it deals with pet food because we have just come off of a pet food crisis, but it doesn't stop there because this contamination doesn't stop with pet food. Sure, we found it in the cans of dog food and cat food, but guess what. It ended up in livestock feed. It ended up moving into the feedlots for hogs, turning into pork products we buy in the store. It ended up in poultry plants, being fed to chickens. We are naive to believe that any problem in the pet food industry can't possibly make it to the human food side of the equation. It can. God forbid that it ever does. We hope we have stopped it in this instance, but it is pure luck if we were able to save ourselves from that calamity this time. We don't want it to happen again.

There are provisions in this amendment which go directly to the pet food issue, provisions which require the FDA to update their labeling standards for pet food, including nutritional and ingredient information, working closely with the American Association of Feed Control so that the representations on the labels of these cans of pet food are honest representations about what is good for your animal and what is safe. Also, it requires that the Secretary of Health and Human Services establish an enhanced system capable of detecting food contamination and outbreaks of pet illness and death.

This amendment also requires the FDA to develop an efficient, effective communication plan to coordinate with veterinarians and consumers, owners across America, so that we can find out if we are dealing with a need for a recall. Recall data would be consolidated and presented in a searchable format. They were recalling pet food so quickly that if you went to the FDA Web site, you had to plow through all of the corporate press releases to figure out just exactly what was a dangerous product. When I mentioned this to the FDA, they changed their Web site, and we put it into law, to make sure they are consumer friendly and have up-to-date information consumers can understand.

We work with the Secretary as well and the States on activities and programs to improve the safety of raw agricultural commodities. We go beyond just pet food into all edible products, agricultural products. What we attempt to do is to have the Secretary share resources with the States to improve State food programs and help States establish standards for inspection. Fifty States, 50 standards, is unacceptable. There should be one scientific matrix we follow so we know that whether the product comes from Oregon or Illinois or New Hampshire, that it is safe.

We also establish something that I think is historic. It applies to pet and human food as well. It is an adulterated food register, to collect information on cases of food adulteration and suspected adulteration that are potentially dangerous and improve the speed

by which consumers learn about them. We want an early-warning system, and in this age of computers and the Internet, we can achieve it.

I believe this is critically important. In this case, there was a Canadian company called Menu which made dog food. Menu discovered in the middle of February that the cats and dogs were turning up their noses at their product, and then they found those that were eating their products started to show signs of illness, and then some of the animals died. Do you know how long it took them to report this to the Food and Drug Administration? Three weeks. Three weeks, while their products spread across Canada and North America, on the shelves of stores, and unsuspecting customers were buying them, they weren't reporting them. Our law now requires reporting within 2 days, and if they fail to report, they face civil penalties, which I hope will be imposed on a timely basis so that we let all companies know this kind of delay is intolerable.

We also do something here that is important. If we find evidence of adulterated food, we report it as well to Homeland Security. Why? Well, Governor Tommy Thompson told us why. When he left as Secretary of Health and Human Services under this administration, he said: I find it unimaginable that someone hasn't tried to use our food supply—the terrorists haven't turned to our food supply to cause injury and death. He understood, as I do, and everyone should at this moment, it is a vulnerability for America we need to avoid. So this food registry will move us into a notification phase so the Department of Homeland Security can at least have notice if there is a problem.

We also require better access to business records for the investigation to get to the bottom of it. Where did it come from? How is it used? How can we contain the need?

We talk about a sense of the Senate in this amendment that points in another direction, maybe going beyond this current crisis into looking at an overhaul of our whole food safety system, and we require the Secretary of Health and Human Services to report annually to Congress with information about their inspections and enforcement.

I am going to yield the floor at this point, and I again thank Senators KENNEDY and ENZI for their help on this important legislation.

I wish to tell my colleagues that there were things I wanted to add in with this amendment, but in the interest of avoiding political conflict and in the interest of not slowing down this important legislation and in the interest of making certain we did achieve something today, I am saving those arguments for another day.

One of them is the issue of mandatory recall, which I think our Government should have the power to do and currently does not. Our Government and its agencies do not have the power to recall contaminated food from the shelves. I believe that law needs to be changed. It is not included in this amendment. We will save that debate for another day.

Again, my thanks to my colleagues.

Madam President, I ask unanimous consent that the pending amendment be set aside, and I send an amendment to the desk and ask for its immediate consideration.

The PRESIDING OFFICER (Mrs. MCCASKILL). Without objection, it is so ordered.

The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Illinois [Mr. DURBIN], for himself and Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, and Mr. NELSON of Florida, proposes an amendment numbered 1022.

Mr. DURBIN. I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The amendment is printed in today's RECORD under ''Text of Amendments.'')

Mr. DURBIN. Madam President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There appears to be a sufficient second.

The yeas and nays are ordered.

Mr. DURBIN. Madam President, before yielding the floor, of course I will leave it to Senator ENZI and Senator KENNEDY for the timing of this rollcall, but I am ready at any time for it to be called after they have had a chance to make a statement.

I yield the floor.

The PRESIDING OFFICER. The Senator from Wyoming is recognized.

Mr. ENZI. Madam President, I thank the Senator from Illinois, Mr. DURBIN, for his tremendous work and creativity and willingness to make revisions to his amendment so that we can clear up outstanding concerns or clarify outstanding concerns people might have had with it. I think we are at the point where that is the case. I would like to make a few comments on it myself.

Food safety is an issue that affects us all. It is not a partisan issue. We all want the safest food supply possible. It is, instead, our shared goal, a goal that requires cooperation and teamwork through a complicated process, and we have had that.

For many of us, the safety and reliability of our food system is something we all too often take for granted. Day by day, we consume our favorite beverages, enjoy a quick snack, or sit down to a meal at a local restaurant. We rely on a system of checks and balances that takes place behind the scenes that we are often unaware of until something goes wrong. Then and only then do we realize how dependent we are on the food safety system that is supported by the activities carried out by the Federal, State, and local government agencies, as well as by the food industry itself. Together, they inspect, test, research, and monitor our food supply from the farm or ranch where it is produced to the family dinner table where it is consumed. The type and amount of oversight they exercise depends on the food product, and the degree of regulatory scrutiny they demand is commensurate with the degree of risk.

In addition to these longstanding authorities and the activities of food safety, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 required the Food and Drug Administration to register food processors, inspect their records, and detain adulterated food. It also requires the Food and Drug Administration to issue regulations to ensure the safety of imported foods.

Food safety has been making news lately. From E. coli in fresh spinach to salmonella in peanut butter to melamine-contaminated pet food, we hear a constant drumbeat of food safety problems.

The United States has one of the best food safety systems in the world, but even in the best of systems, there is room for improvement. Those improvements can take many forms. For example, we can address how food becomes contaminated in the first place, and we can make advances in the processing and handling of food. Our surveillance, testing, and reporting systems represent areas we should evaluate, as well as internal and external communications. Interagency cooperation and coordination between Federal and State officials is critical in identifying, tracking, and responding to outbreaks of foodborne illness.

The amendment offered by my colleague, Senator DURBIN, contains several important elements in that response, but it is the beginning, not the end, of the process of food safety. This amendment does a number of important things. It establishes standards for pet food and sets up early-warning systems for any problems with pet food. The amendment improves communications systems about all food recalls, and it coordinates State and Federal activities on fresh and processed produce. Finally, the amendment creates a database of instances of adulterated food so that the FDA can better track patterns of problems and target its limited resources where they are most needed.

I am pleased we are able to work across party lines to develop an amendment today that we can all support, and I ask unanimous consent to be a cosponsor, along with Senator ALLARD.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. ENZI. However, there is much more work to be done. This amendment is a good first step on the road to a comprehensive response to food safety.

In March 2005, Senator KENNEDY and I announced that we were working to develop a comprehensive response on another FDA issue, which is drug safety. The bill on the floor this week is a direct result of that announcement and

that pledge to work together. So when I pledge today to work to develop a comprehensive response on food safety, you can have some sense that I do mean that. I want my colleagues to work quickly and diligently to get this amendment to the point where we can accept it. I know we have it scheduled for a vote at the moment, too.

Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I wish to join with Senator ENZI and thank our friend and colleague, Senator DURBIN, for his strong leadership on this issue. This is an issue of enormous importance to families across the country.

As Senator ENZI just mentioned, over a year ago we made a strong commitment to the Senate that we were going to work on this drug safety issue, and we have come here in a bipartisan way to put forward a very strong bill that will ensure greater safety for American families in the area of prescription drugs. I think we are here to say that we will join with our friend and colleague from Illinois to build on what is an enormously important amendment and commitment to ensuring that we are going to have food safety as well as pet food safety in this country.

I think this amendment, as has been outlined by Senator DURBIN and Senator ENZI, reaches the heart of the challenges we face. One is on the issue of surveillance. We understand that is an essential aspect, whether it is food safety or prescription drugs, or whether it is in the area of avian flu, bioterrorism—whatever the challenge that is out there, surveillance is the first thing that needs to be done. We know that today the system is grossly inadequate.

Second, we know the information about food and food safety is scattered through a number of agencies and through a number of different kinds of delivery systems, and that the coordination between the Federal and State is loose. In all of these areas, this amendment addresses these issues and questions in a very effective way, to bring common sense to and put real teeth into the safety provisions.

The pet food standards that are in this legislation are strong and effective and would be very much appreciated by all Americans who are concerned about this issue. The standards are variable at the present time. The reporting is not good today, and this particular amendment is particularly responsive to that kind of challenge.

Finally, this addresses the central concern all of us have read about and are concerned about, which the Senator has spoken to, and that is the issue of importation. When you add up all of those kinds of elements, we find this is a very solid and meaningful amendment. I think it strengthens the legislation immensely. We have every purpose, as we move forward, to find ways we can provide even a greater kind of protection and safety to the food supply for American families.

I commend the Senator from Illinois. I think we will be ready to have a vote on this at the earliest time.

The PRESIDING OFFICER. The Senator from Illinois.

Mr. DURBIN. Madam President, I ask unanimous consent that Senators KOHL, CANTWELL, SCHUMER, and BIDEN be added as cosponsors of this amendment.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DURBIN. Madam President, I ask unanimous consent that the Senate proceed to vote in relation to the Durbin amendment No. 1022; that no other amendments be in order prior to the vote; that the time until then be equally divided and controlled between Senators KENNEDY and ENZI; and that the vote be scheduled for 4:30 p.m.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. DURBIN. Madam President, I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, we expect the vote at 4:30, for our colleagues. After that, we are going to have a conversation with those who have been primarily interested and concerned about the whole issue of biologics. So I give the assurance we are going to address that issue in a timely way. That will ultimately be part of this legislation.

We also will be able to report on progress we have made on several other amendments. There are a few items that are going to necessitate our attention through the evening. We had a very good debate earlier today on the children's provisions; we had an important vote and discussion on that.

This addition this afternoon is enormously important, and I think the time that has been taken to work through this legislation has made it even stronger and better than I think it otherwise might have been. I am grateful to all of our colleagues who are working with us on both sides of the aisle, and particularly the staffs. We are moving forward. We are going to be busy this evening trying to work through some of the items, and we will have the cloture vote tomorrow and the follow-on Cochran amendment.

There is a glimmer in sight about reaching a conclusion to this legislation. Again, we are very appreciative of all who have helped us up to this point.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DURBIN. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

MODIFICATION TO AMENDMENT NO. 1022

Mr. DURBIN. Madam President, we found a typo on page 5 in the amendment that we want to clear up before the amendment is considered.

I ask unanimous consent to modify the amendment as submitted to the Senate. I send the modification to the desk.

The PRESIDING OFFICER. Without objection, the amendment is so modified.

The modification is as follows:

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. _04. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produce so that State food safety programs involving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

Mr. DURBIN. Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. KOHL. Madam President, I rise today and would like to briefly speak about Senator DURBIN's amendment regarding food safety. I was happy to cosponsor this amendment, and I agree with all of the sentiments expressed by the Senator earlier today.

This amendment deals with many of the underlying problems that allow food safety issues, such as the ones we have dealt with in recent months that have affected not only humans, but their pets as well.

It requires the FDA to set standards for pet food and to update them as necessary, and it directs the Secretary of Health and Human Services to establish a system capable of detecting pet food contamination and outbreaks of pet illnesses and death—this will prevent the type of confusion that continues to surround the recent melamine outbreak, and will help detect these problems much earlier. It requires FDA to develop effective communication plans to coordinate with stakeholders during outbreaks of both pet and human foods, so people know what is going on—quickly—and know what to do. It directs the Secretary to work with States to collaborate on activities and programs that assist in improving the safety of raw agricultural products such as spinach, which was the cause of a major food safety recall last fall. Importantly, it requires FDA

to establish a registry to collect information on cases of potentially dangerous food adulteration to help get any dangerous food off of the shelves more quickly and to allow FDA to target inspection resources where most needed.

This amendment does many important things—and takes many important first steps. I know that Senator DURBIN would have liked this amendment to go a little further, and I agree with his sentiments, but it is important to at least take the first step.

In March of this year, I held a hearing in Madison, WI, on food safety issues at the FDA. The Commissioner of FDA attended, as well as the Director of the FDA's Center for Food Safety. At that time, I pointed out that outbreaks of foodborne illness caused by produce have doubled since 1998. During this same time, the FDA's food budget has suffered. The number of people getting sick is going up, but the number of inspections and food safety tests being conducted is dwindling. So too are the number of food inspectors and overall staff at the FDA's Center for Food Safety. Imports have risen dramatically over the years, but the FDA is only able to inspect less than 1 percent of them.

Events after that hearing seemed to exacerbate what I pointed out. The recent pet food scare, and the ongoing melamine investigation, serve as constant reminders that we have been taking this issue for granted, assuming that the FDA has the authority and funding necessary to do its job, when that is clearly not the case.

Senator DURBIN's amendment begins to take care of some of the problems with FDA authority and actions.

As the chairman of the Agriculture Appropriations Subcommittee, which has jurisdiction over the FDA's budget, it is my job to make certain that the FDA has the money to carry out its vital role of protecting our food. The Food Center at FDA doesn't have user fees from industry to boost its funding—it all comes from the Congress, and has been stagnant for far too long.

I have been working diligently to make sure that when the fiscal year 2008 Agriculture Appropriations bill is written, food safety will be one of its highlights. I do not believe the administration has ever requested enough funding for food safety at the FDA, this year notwithstanding. I plan to correct that. It may not happen all in the first year being fiscally responsible can be tough—but it will happen. We will provide a significant increase to the FDA this year, so they can implement some of what Senator DURBIN's amendment proposes, and quite simply, so they can hire inspectors where they are needed, to do the necessary research to prevent outbreaks from occurring wherever possible, and so we don't continue to see large recall notices in our newspapers every day. It is not a problem that can be fixed immediately, but I fully intend to meet my end of the obligation in making sure that FDA has the money that it needs, and can use responsibly, to tackle this problem head on.

Mr. DURBIN. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DURBIN. Madam President, pursuant to the unanimous consent request, I ask that the roll be called on amendment No. 1022.

The PRESIDING OFFICER. Under the previous order, the question is on agreeing to amendment No. 1022, as modified, offered by the Senator from Illinois.

The yeas and nays have been ordered. The clerk will call the roll.

The assistant legislative clerk called the roll.

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from Connecticut (Mr. DODD) and the Senator from South Dakota (Mr. JOHNSON) are necessarily absent.

I further announce that, if present and voting, the Senator from Delaware (Mr. BIDEN) would vote ''yea.''

Mr. LOTT. The following Senators are necessarily absent: the Senator from Kansas (Mr. BROWNBACK), the Senator from South Carolina (Mr. GRAHAM), and the Senator from Arizona (Mr. MCCAIN).

The result was announced—yeas 94, nays 0, as follows:

[Rollcall Vote No. 149 Leg.]

YEAS—94

Akaka	Durbin	Murkowski
Alexander	Ensign	Murray
Allard	Enzi	Nelson (FL)
Baucus	Feingold	Nelson (NE)
Bayh	Feinstein	Obama
Bennett	Grassley	Pryor
Bingaman	Gregg	Reed
Bond	Hagel	Reid
Boxer	Harkin	Roberts
Brown	Hatch	Rockefeller
Bunning	Hutchison	Salazar
Burr	Inhofe	Sanders
Byrd	Inouye	Schumer
Cantwell	Isakson	Sessions
Cardin	Kennedy	Shelby
Carper	Kerry	Smith
Casey	Klobuchar	Snowe
Chambliss	Kohl	Specter
Clinton	Kyl	Stabenow
Coburn	Landrieu	Stevens
Cochran	Lautenberg	Sununu
Coleman	Leahy	Tester
Collins	Levin	Thomas
Conrad	Lieberman	Thune
Corker	Lincoln	Vitter
Cornyn	Lott	Voinovich
Craig	Lugar	Warner
Crapo	Martinez	Webb
DeMint	McCaskill	Whitehouse
Dole	McConnell	Wyden
Domenici	Menendez	
Dorgan	Mikulski	

NOT VOTING—6

Biden	Dodd	Johnson
Brownback	Graham	McCain

The amendment (No. 1022), as modified, was agreed to.

Mr. DURBIN. Madam President, I move to reconsider the vote and to lay that motion on the table.

The motion to lay on the table was agreed to.

Mr. VITTER. Madam President, I ask unanimous consent that the pending amendment be set aside and that I may call up amendment No. 983.

The PRESIDING OFFICER. Is there objection to setting aside the pending amendment?

Mr. KENNEDY. Reserving the right to object, I suggest the absence of a quorum.

The PRESIDING OFFICER. The Senator from Louisiana has the floor.

Mr. KENNEDY. I object to the unanimous consent request.

The PRESIDING OFFICER. Objection is heard.

Mr. KENNEDY. Madam President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. KENNEDY. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 983

Mr. VITTER. Madam President, I renew my unanimous consent request that any pending amendment be set aside and that amendment No. 983 be called up.

The PRESIDING OFFICER. Is there objection?

Without objection, the amendment is set aside, and the clerk will report.

The assistant legislative clerk read as follows:

The Senator from Louisiana [Mr. VITTER] proposes amendment numbered 983.

Mr. VITTER. Madam President, I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To require counterfeit-resistant technologies for prescription drugs)

At the end of subtitle E of title II, insert the following:

SEC. ___. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to

identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of nonvisible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

Mr. VITTER. Madam President, first, in terms of laying the groundwork for this amendment, let me speak very briefly about the broader reimportation debate. I commend my colleagues who have brought this issue to the floor, and I certainly join them in pushing strongly for reimportation language in this bill. I have worked with many Members of this body, Republican and Democrat, on this issue since I was elected, including the primary authors of the reimportation amendment that we will be voting on later under this bill. I certainly want to join many voices, again, on both sides of the aisle, in terms of the need for this sort of important legislation that helps stabilize and bring down the price of prescription drugs.

My amendment, No. 983, to which I will now turn, is very directly related to that. It is not a reimportation amendment per se, but it goes directly to one of the primary issues that opponents of reimportation regularly bring up, which is safety. My amendment, No. 983, is about tamper-resistent technology—packaging technology—which can go a long way in meeting all of those safety concerns. I think there are many legitimate ways we can meet them, but this is a very effective and a very economical way to help meet any of those concerns.

This amendment, No. 983, would require the incorporation of counterfeit resistent technologies into the packaging of prescription drugs. Not just reimported prescription drugs, but all prescription drugs because counterfeit prescription drugs is an issue not simply with regard to reimportation. Specifically, wholesale prescription drugs would contain RFID radio-tagging technology, tamper-resistent packaging, and blister security packaging, when possible.

This is language directly from my legislation of the last Congress, the Reducing Fraudulent and Imitation Drugs Act. Of course, the purpose of that bill and this amendment is to address that safety concern, which comes up in a number of contexts, but certainly including reimportation. By ensuring that prescription drugs are authentic, this amendment would ensure the drug supply within the United States, as well as prescriptions reimported from Canada and other industrialized nations, are indeed safe.

Again, the amendment would require that such technologies be used exclusively to authenticate the pedigree of prescription drugs. It would actually prohibit such technologies from containing or transmitting any identifying information of a health care practitioner or consumer or any advertisement or information about indications or off-label uses. So it is specifically for authentication. This is what you are getting. It cannot be used for any other purpose that might bring up privacy or other concerns.

It would also require prescription drug shipments to include a label on the shipper container that incorporates similar packaging technologies.

Finally, the amendment would require the Secretary to publish a national specified list of susceptible prescription drugs consisting of not less than 30 of the most frequently counterfeited prescription drugs in the United States. This would provide significant assistance to efforts by U.S. law enforcement and the FDA to deal with this issue.

I hope all of us can join together around this very promising new technology that can help meet any legitimate safety concerns out there. Much more broadly speaking, of course, I certainly hope we come together to pass broad-based reimportation language in this bill, which I have supported well before coming to the Senate and, being in the Senate, certainly support in this context.

Mr. NELSON of Florida. Will the Senator yield?

Mr. VITTER. Certainly I yield.

Mr. NELSON of Florida. Certainly the Senator remembers when he and this Senator from Florida introduced an amendment a year ago to allow the importation of drugs from Canada for a limited supply, stated as 90 days or less, for personal use, and how we passed that here in the Senate. It was watered down once it got into conference in the House. It only allowed Americans going to and from Canada to carry drugs in that capacity—personal use, limited supply.

Now we are going to be approaching this, and I ask the Senator, he is joining on the Dorgan amendment on the reimportation as one of the cosponsors of this amendment, is that correct?

Mr. VITTER. I honestly do not know if I am technically a cosponsor. I am certainly supporting it. I supported our common efforts for several years. Many of the elements of my separate bill have been incorporated into the Dorgan-Snowe language, going back to last year. So we are certainly all working in concert.

I again recognize and thank the Senator from Florida for our common work on the amendment last year, which he referenced.

Mr. NELSON of Florida. If the Senator will further yield, does he remember in the debate we had when we agreed to that amendment, that Customs had even gotten into the act and was seizing thousands and thousands of these pharmaceutical packages for individual use and limited supply? Of course, in my State of Florida that happened with great frequency since a number of our senior citizens, in fact, do that. Finally we got Customs to come out and say they were no longer going to do that, they were going to defer it to the Food and Drug Administration. The Acting Administrator of the FDA had actually said no, they didn't have an objection to a limited supply for personal use, whether it was ordered by phone or Internet or by the mail, or someone walking across the border.

Isn't it interesting that after all of that—and we finally agreed to the amendment—we still come to the year 2007 and we are having to address this issue again?

Mr. VITTER. I agree with the Senator, absolutely. We should have taken care of this a long time ago. But we are where we are, and I certainly urge my colleagues on both sides of the aisle to address this in a full and comprehensive way.

Mr. NELSON of Florida. The Congressional Budget Office is estimating that this legislation is going to save consumers in this country $50 billion over the next 10 years because so often the price they get it for at the retail outlet here is twice what they can get it for from a Canadian pharmacy.

It has been a pleasure for me to work with the Senator. I look forward to working with Senator DORGAN on his amendment.

Mr. VITTER. I thank the Senator from Florida. I certainly have similar beliefs.

I urge adoption of this amendment I presented and certainly urge my colleagues to also support the broader reimportation language, as will I.

I yield the floor.

The PRESIDING OFFICER (Mr. OBAMA). The Senator from Wyoming.

Mr. ENZI. I thank the Senator from Louisiana for his patience on this amendment, and also his understanding that he would work with my staff and the staff of Senator KENNEDY to see what can be done to make our drug supply safer. I appreciate that.

I also thank him for all the efforts he has made on behalf of the Louisiana turtle farmers, which was a new industry to me—although they have been exporting turtles all over the world for years—for the work he did drafting and putting together a mechanism for eliminating salmonella in turtles so they can be, once again, pets in the United States.

The PRESIDING OFFICER. The Senator from New York.

Mr. SCHUMER. Mr. President, I rise to engage in a colloquy with my colleagues from Utah, New York, Massachusetts, and Wyoming on biologics. I thank every one of them for their cooperation and help as we move forward.

Mr. President, I rise today with my colleagues to speak about biologic drugs, a large and growing sector of the drug market. Biologic drugs can cost tens of thousands of dollars a year for a single patient, and treat devastating diseases such as cancer and its complications. There is currently no clear pathway for lower cost competitors to biologic drugs to enter the market, as there is for generic versions of traditional chemical drugs. I have introduced a bill to create such a pathway. I am glad to see my friends Senator KENNEDY, Senator ENZI, and Senator HATCH on the floor to discuss this issue with us. I yield to my colleague from Utah.

Mr. HATCH. I am happy to discuss this issue with my colleagues. As they are aware, this has been my high priority for a number of years, given that I am the author with Representative HENRY WAXMAN of the Drug Price Competition and Patent Term Restoration Act—or ''Hatch-Waxman''. The Schumer-Clinton bill, which I know has been introduced by Representative WAXMAN in the House, is an important contribution to this dialogue. I want to work to reach an acceptable compromise on an expedited basis, and it is clear to me it must be a bipartisan effort.

Mrs. CLINTON. I thank the Senator for his leadership on generic drugs and for his presence here today. In 1984 when the Hatch-Waxman generic drug law was written, very few biologic drugs existed and there was no need to empower the FDA to approve lower cost versions of existing biologic drugs. This is no longer the case and it is time to enact legislation that will allow the FDA to approve safe and effective follow-on versions of biotech drugs.

Mr. KENNEDY. I thank my colleagues and I agree that creating a pathway for follow-on biologics is an important issue worthy of our consideration.

Mr. SCHUMER. I say to Chairman KENNEDY, the junior Senator from New York and I stand ready to offer a bipartisan amendment to this bill that would establish a pathway for follow-on biologic drugs. We would prefer to work with you, and with the distinguished Senators from Wyoming and Utah. To that end, we would like to work together to discuss a pathway that protects patient safety, enables consumer access to more affordable biologic drugs, and provides appropriate incentives for continued innovation of lifesaving drugs.

Mrs. CLINTON. I agree with my friend Senator SCHUMER, and note with gratitude that the HELP Committee began bipartisan discussions on how to accomplish this goal. And while I was disappointed that follow-on biologic legislation was not included during committee consideration of S. 1082, it was in good faith that I did not offer an amendment with the understanding that our bipartisan efforts would continue.

As my colleagues and I move forward on this important effort, I think it is important to identify the key principles that must be contained in the legislation: We must provide the FDA with the authority and flexibility to approve biopharmaceuticals subject to a workable, abbreviated approval pathway that is efficient, effective and scientifically grounded. We must also include measures to ensure timely resolution of patent disputes, as well as adequate incentives for continued innovation.

Mr. KENNEDY. I assure the Senators from New York that the conference report on the FDA Revitalization Act will include a pathway to follow-on biologics that has been reported out of the HELP Committee and that is acceptable to the Senators from New York. I plan to hold a markup on this issue on June 13.

Mr. ENZI. The heart of the debate is how to construct a regulatory framework so that biologic drugs can be safely available under an accelerated pathway. It is more difficult to approve biosimilars than to approve generic versions of typical drugs. The balance we are trying to find is a compromise that promotes access with innovation, while also maintaining the high standards of safety at the Food and Drug Administration.

Biologics are complex molecules modeled after key processes occurring daily within the human body. One analogy is that if a typical drug was a 3 bedroom, 2 bath starter home, a biologic would be a skyscraper. The size, scope and complexity are completely different. The nomenclature is, too. As key scientists stated at our HELP Committee hearing on this topic, these are not generic biologics but biosimilars.

With many drugs, we can describe their structure with a high degree of precision—but not with follow-on biologics. You can't make an exact ''copy'' of a biologic, like you can for most typical generic drugs. For example, if I was to try to build the skyscraper of a biologic without the blueprints, as any generic company would need to do to create a follow-on biologic, I would have to ensure that every copy was identical or there could be fatal results.

Because of this, science must be an essential part of any safety standard.

One piece out of place would cause the entire structure to fall.

But to be clear, a safe pathway for an accelerated approval process for biologics, that also preserves innovation, is possible. It is not just me who believes it—the FDA, generic and pharmaceutical industries have all said so as well. I have been working across party lines with Senators HATCH, KENNEDY and CLINTON to develop legislation that does just that. Our staffs have been working tirelessly on this topic: individually meeting with experts and stakeholders; and as a group, talking with experts from the United States and global leaders. After all, we want the same end result—legislation that ensures medicines are safe and affordable, and that medical innovation continues to flourish.

I have a track record of working across party lines to build consensus and find common ground on tricky legislative issues. I know that with a little more time, and through regular order, we will develop a bipartisan package that accomplishes our common goals.

I concur with the chairman and am committed to moving a bipartisan bill through the HELP Committee in the near future with the goal that it can be joined with the conference on the FDA Revitalization Act.

Mr. HATCH. I look forward to working with my colleagues to include bipartisan follow-on biologics legislation in the conference agreement on the FDA Revitalization Act. It is clear that consumers would benefit tremendously from an abbreviated pathway for consideration of biosimilar products. Any effort, though, must be based on a sound understanding of the science involved and it must contain incentives for development of the innovator products which will be copied.

Mr. SCHUMER. I thank my colleagues for these commitments. I look forward to working together with Chairman KENNEDY, Senator ENZI, Senator CLINTON, and Senator HATCH to develop workable legislative language that can be scheduled for a June 13 markup in the HELP Committee and included in the FDA Revitalization Act conference report.

AMENDMENT NO. 1025

With that, I ask unanimous consent to set aside the pending amendment and send my amendment, a sense of the Senate, to the desk.

The PRESIDING OFFICER. Without objection, it is so ordered. The pending amendment is set aside. The clerk will report the amendment.

The bill clerk read as follows.

The Senator from New York [Mr. SCHUMER], for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY, proposes an amendment numbered 1025.

Mr. SCHUMER. I ask unanimous consent the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To express the sense of the Senate with respect to follow-on biologies)

At the end of the bill, add the following:

SEC. ___. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) legislation should be enacted to—

(A) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(B) ensure that patient safety remains paramount in the system;

(C) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that also includes measures to ensure timely resolution of patent disputes; and

(D) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

Mr. SCHUMER. Mr. President, I ask that the amendment be adopted.

The PRESIDING OFFICER. Is there further debate on the amendment?

If not, the question is agreeing to the amendment of the Senator from New York.

The amendment (No. 1025) was agreed to.

Mr. KENNEDY. Mr. President, I move to reconsider the vote by which the amendment was agreed to.

Mr. ENZI. Mr. President, I move to lay that motion on the table.

The motion to lay on the table was agreed to.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, I thank all of our colleagues for their cooperation and their help on this particular subject matter. It is a matter of enormous importance, incredible consequence, and enormous complexity. We thank them for all of their help and assistance in bringing us to where we are so that the Members understand better where we are. We are absolutely committed to having that hearing and having the results of that go into our conference.

I am enormously appreciative of the patience and the cooperation we have received. I am grateful again to all of those here, colleagues on both sides, for their cooperation in helping us move this forward.

I thank the Senator from Utah. I want to congratulate him. He is receiving an honorary degree tomorrow from a great university in his State. We were talking about biologics. We think of the Hatch-Waxman proposal and acknowledge his work, attention, and help in the fashioning of that important piece of legislation, particularly when we are thinking about his involvement in the biologics, a clear indication we are going to have some good bipartisan support and we are going to have a team that has a breadth of knowledge and understanding of these kinds of subject matters. We wish him well on his trip to Utah and congratulate him on his degree tomorrow.

Mr. HATCH. Will the Senator yield?

Mr. KENNEDY. I will yield.

Mr. HATCH. Mr. President, I thank my dear friend and colleague. It is so nice of him to say that. I take tremendous interest in this bill, as I do every piece of legislation, but this bill in particular.

I congratulate the chairman and the ranking member for the way they have conducted not only the committee through this process but this bill itself. I hope this bill will pass and that we can correct whatever needs to be corrected, and that we will be able to do this follow-on biological work together. If we can do that, this will be a major breakthrough bill, and will do a great deal of good for the FDA. If that happens, then I think the chairman and the ranking member deserve a great deal of credit. I am very grateful my friend from Massachusetts has been so kind to me today.

The PRESIDING OFFICER. The Senator from New York is recognized.

Mr. SCHUMER. I add my thanks to the chairman and ranking member of the HELP Committee for all of their help and constructive resolution of this. It allows us to pass a very important FDA bill and at the same time move on the biologics.

I join my colleague from Massachusetts in congratulating my friend from Utah on his honorary degree. He will get a doctorate, I imagine, and perhaps after he will not only get an honorary degree and be a doctor but maybe he can even create a few biologics after we pass the law.

The PRESIDING OFFICER. The Senator from Utah is recognized.

Mr. HATCH. Mr. President, to say the distinguished Senator from New York knows how to stick it to a person on the floor is all I can say.

I am grateful for this friendship and grateful for his and Senator CLINTON's work on this as well, and willingness to work together in a bipartisan way. This is big-time stuff. If we get it right, it will surely do a lot of good, as Hatch-Waxman has done over the last 23 years.

The PRESIDING OFFICER. The Senator from New Mexico is recognized.

Mr. DOMENICI. Mr. President, I ask unanimous consent that I be permitted to speak for up to 10 minutes as in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

HONORING JACK VALENTI

Mr. DOMENICI. Mr. President, I was present yesterday at the funeral mass at St. Matthew's for Jack Joseph Valenti. I did not know he had a middle name, Joseph, but I am learning more

and more about him now after his passing. I was a friend of his. I thought I knew much about him. But the more I read, the more I find out what a spectacular man and a marvelous life he lived.

I thought I would share with the Senate, since somebody said at the mass, as they were permitted to speak—they were one of the few who were selected—I would bet that everybody in this church would like to come up here and be given 10 minutes to say something about their friend Jack Valenti.

That person who said that was absolutely right. That is exactly how I felt sitting there: Wouldn't it be nice if I could walk up there and tell all of these people and whoever else was listening, share what I knew about him. Of course, that was not to be.

But today I am going to do that in the Senate for a few minutes, and tell the Senate about how this man, who was known to try to help everybody in very different circumstances, how he came to know me and how I came to know him.

I was elected in 1972, and of course right now it sort of goes by easy; my last name is Italian. You know it was pretty well understood when I was elected that I was Italian—DOMENICI from out in the West, when all of the Italians who are in politics are from out here in the East, from New York, New Jersey. People wondered: Where did that guy come from?

Well, the truth is, Jack Valenti also wondered. He called me on the telephone and said: Are you PETE DOMENICI, the new Senator?

I said: Yes, sir. He told me who he was. He said: You know, I don't know you, you don't know me, but you probably could easily find out who I am. All I want to tell you is: I would like to help you.

Now, we are thousands of miles away. I have never seen him. I was elected. He is telling me on the phone: I would sure like to help you if I can.

Of course, I said: Give me your phone number and let me get ahold of you. By the time I asked a few people, they said: You are lucky. He is one of the people in Washington who knows more about what is going on here, than the man who called you.

I quickly arranged a meeting at the Willard Hotel. It was prior to its remodeling so it wasn't as nice as it is today. But I didn't know better. I made arrangements there. Then I invited him to come and visit. Here comes Mr. Valenti to come and meet me there at the Willard Hotel. I mean, it was a joyous occasion. You would have thought I was a long-lost relative. It was all because he was glad to see a young Italian boy get elected to the Senate. He came from an immigrant Italian family himself.

So we talked. He said: Well, let me try to help you. I would like to tell you what his first offer was. Let's go meet some people and see what we can do about talking about the committee assignments you might get.

I told him: Here is the one I want. I want the Joint Committee on Atomic Energy, because that has a lot to do with my State. So we talked and we worked. Sure enough, we were making a little headway and we read that the House had had a meeting of leadership and they had decided there would no longer be a Joint Committee on Atomic Energy so they abolished it. So all of my work and all of his work was for naught, because we decided we were not going do business in a joint manner on atomic energy.

But what a joy it was, the first meeting—not successful in terms of our mission but greatly successful in terms of establishing our friendship.

I will mention two things in my life and then yield to the Senator.

Years later, one of my sons was working here in Washington. Some people know him. His name is David. He had established and built a charter school here, a school in town that ended up being called Maya Angelou School, a school named after the great poet laureate. And, of course, as you would guess from the name of the school, it was sort of a special school. It was a charter school my son started with the help of another man, and it was for the purpose of taking the troubled young teenagers, who were either going to jail, because they had already done enough bad things, criminal things, they were going to jail, or the judge would assign them to this school.

This son of mine built this charter school. It got to be a pretty good size. At a point in time he was opening a new building, and he called me and talked to me and said: You know, maybe I could get some help from somebody for some computers for these students.

This is my second meeting with my friend. I called him up and said: I would like you to meet my son David. I told him why. He said: Of course. They met, talked on the telephone. Within a very short period of time, the charter school I am describing to you, which was a very difficult thing for my son and his friend to run—had a great success. He opened two of them; two of them exist in Washington now. But, lo and behold, shortly after this meeting and our discussion with Mr. Valenti, the computers that were needed for the school to totally fill out all of the computer needs arrived as a special donation from somebody.

Well, of course, we know the somebody. We found out later our friend Mr. Valenti worked to get in touch with those who could help donate to these students' needs.

He is gone now, but we do not know how many thousands of things like this he did during his life, along with the other things that are more notorious that he did in his job, which was a very open and public job for many years of his life, and a hard one when he worked for the motion picture industry. So we do not know how many people he helped. But I thought maybe I would borrow this few minutes of the Senate's time to put down my thoughts for his wife, who I obviously did not know as well as I knew him. But I did get to know her. I saw her at the funeral. Of course, she is having a difficult time. I do not know their children. I did have a chance to talk to his wife and say I hope that everything went well. I think it will. With this, I say maybe no one else in the Senate will do this, but as part of my day, I salute Mr. Jack Valenti for all he did, and I am very grateful I had the chance to say a few words about him.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Mr. President, I thank my friend from New Mexico. I had the good opportunity to attend that service as well. I will include my comments about Jack Valenti. He was a dear and valued friend of the Kennedys. We went back a long time with Jack, to the 1960 campaign. It was a long friendship, that endured a lot of very glorious times and difficult and challenging ones as well. He was a person of great purpose, with a love for his country, devotion to his industry, which he represented so effectively, and a wonderful friend to many of us. I thank the Senator for his comments.

Mr. President, for the benefit of our Members here, we are going to recess shortly and go over to 9:30 tomorrow morning. The hour before the cloture vote will run from 9:30 to 10:30, and we will yield a half hour on our side to the proponent of the amendment, Senator DORGAN. Then at 10:30 or just about 10:30 we expect we will have a roll call vote on the Dorgan amendment, or the motion to invoke cloture on the Dorgan amendment. Then, depending on how that comes out, we will move ahead to hopefully conclude work on some of the items we have had good discussions about today—the Stabenow amendment. I am grateful to Senator STABENOW. We spoke about this earlier in the day. We have worked with her and made some very important progress and are grateful to her for her cooperation.

We indicated now to the membership how we are going to proceed on the extremely important item of biologics. We now have the drug safety. We have enhanced this bill with food safety. We are going to address in our conference the issue of biologics. This is going to be an extremely important pathway. We have been working with Senator ROBERTS and Senator HARKIN on the direct consumer advertising issue. There are some very important constitutional issues. I am grateful to Senator ROBERTS for his cooperation and help. Senator KOHL has an amendment on reverse payments. There is Senator VITTER's amendment and potentially one or two others that Members have indicated they are giving thought to offering, but haven't decided whether they would.

We are getting close to the end of this, but we still have important matters to do. We are going to try to work with our colleagues. We have made great strides in the evenings. I am very grateful to Senator ENZI and particularly to our staffs who have, each evening, including through the weekend, worked tirelessly to try and ease the differences on many of these amendments and have done a brilliant job. This legislation is extraordinarily important. We have had several amendments, important amendments, but we have also worked out some others that have strengthened the legislation.

In a few moments, we will go into adjournment until tomorrow. But Senators should look forward to the debate at 9:30 and vote at 10:30 on the cloture petition relative to the Dorgan amendment.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. KENNEDY. I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, for the information of the Members, there will be no further votes this evening.

The PRESIDING OFFICER. The Senator from Oklahoma.

Mr. INHOFE. Mr. President, I ask unanimous consent that the pending amendment be set aside for the consideration of amendment 988.

Mr. KENNEDY. If the Senator would withhold, we have a pending amendment. I will have to object until we clarify exactly where we are. Would the Senator give us 30 seconds?

Mr. INHOFE. That would be fine. My intention was to set aside the pending amendment so I could consider this. Then set this aside and go back to the pending amendment.

Mr. KENNEDY. I have no objection to that.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 988

Mr. INHOFE. I thank the Senator from Massachusetts for his tolerance.

Mr. President, I introduced last year a bill I called the Child Medication Safety Act. We are offering it as an amendment to this underlying bill. It is my anticipation that we will get a vote on it ultimately. This is to protect children and their parents from being coerced into administering a controlled substance or psychotropic drug in order to attend school. The House passed their version of H.R. 1790 by 407 to 12 under suspension of the rules in November of 2005.

Parents today face many challenges when raising their children, one of which is ensuring that their children receive the best education possible. My views on education come from a somewhat unique perspective in that my wife Kay was a teacher at Edison High School. My daughters are both teachers. I can assure my colleagues that I am one of the strongest supporters of quality education. However, it has come to my attention that schools have been acting as physicians or psychologists by strongly suggesting that children with behavioral problems be put immediately on some form of psychotropic drugs. Schools and teachers are not equipped to make these diagnoses and should make it mandatory for the student to continue attending the school. This is clearly beyond their area of expertise. Therefore, I am introducing this legislation to ensure that parents are not required by school personnel to medicate their children.

The Child Medication Safety Act requires, as a condition of receiving funds from the Department of Education, that States develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription as a condition of attending school. It should be noted that this bill does not prevent teachers or other school personnel from sharing with parents or guardians classroom-based observations regarding a student's academic performance or regarding the need for evaluation of for special education.

Additionally, this bill calls for a study by the Comptroller General of the United States reviewing: No. 1, the variation among States in the definition of psychotropic medication as used in public education; No. 2, the prescription rates of medication used in public schools to treat children with attention deficit disorders and other such disorders; No. 3, which medications listed under the Controlled Substances Act are being prescribed to such children; and, No. 4, which medications not listed under the Controlled Substances Act are being used to treat these children and their properties and effects. This GAO report is due no later than 1 year after enactment of this act.

I believe it is an extremely important amendment. It protects the rights of our children against improper intrusion regarding health issues by those not qualified. If a parent or guardian believes their child is in need of medication, then they ought to have the right to make that decision and consult with a licensed medical practitioner who is qualified to prescribe an appropriate drug. I am hoping others will join me in support of the amendment. It is a parental rights amendment that should be supported by all.

With that, it is my intention that we will be putting this in line to get a vote. I ask unanimous consent now to return to the previous pending amendment.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. I thank the Senator for his cooperation. I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. GREGG. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. GREGG. I understand the Senator from Oklahoma wants to go into morning business to make a statement. I ask unanimous consent that after he has completed his statement, that I be recognized for purposes of offering my Internet pharmacy protection and safety bill to the underlying bill.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. INHOFE. Mr. President, may I ask a point of inquiry of the Senator from Massachusetts. Apparently the desk is not in agreement with what we did. We set aside the pending amendment for consideration of my amendment which I brought up and presented. Then we returned to that amendment. I would like to ask the Chair if that is accurate.

The PRESIDING OFFICER. The Senator did not offer his amendment. The Senator may offer his amendment, but it was not offered.

Mr. KENNEDY. I ask unanimous consent that his amendment be at the desk and be subject to being called up.

The PRESIDING OFFICER. The clerk will report.

The legislative clerk read as follows:

The Senator from Oklahoma [Mr. INHOFE] proposes an amendment numbered 988.

Mr. INHOFE. I ask unanimous consent that reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To protect children and their parents from being coerced into administering a controlled substance in order to attend school, and for other purposes)

SEC. . CHILD MEDICATION SAFETY.

(a) REQUIRED POLICIES AND PROCEDURES.—

(1) IN GENERAL.—As a condition of receiving funds under any program or activity administered by the Secretary of Education, not later than 1 year after the date of enactment of this section, each State shall develop and implement policies and procedures prohibiting school personnel from requiring a child to obtain a prescription for substances covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug as a condition of attending school or receiving services.

(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed to create a Federal prohibition against teachers and other school personnel consulting or sharing classroom-based observations with parents or guardians regarding a student's academic performance or behavior in the classroom or school, or regarding the need for evaluation for special education or related services under section 612(a)(3) of the Individuals with Disabilities Education Act (20 U.S.C. 1412(a)(3)).

(3) PROHIBITION OF PAYMENT OF FUNDS.—No Federal education funds may be paid to any local educational agency or other instrument of government that uses the refusal of a parent or legal guardian to provide a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) or a psychotropic drug for such individual's child

as the basis of a charge of child abuse, child neglect, education neglect, or medical neglect until the agency or instrument demonstrates that it is no longer using such refusal as a basis of a child abuse, child neglect, education neglect, or medical neglect charge.

(b) DEFINITIONS.—In this section:

(1) CHILD.—The term ''child'' means any person within the age limits for which the State provides free public education.

(2) PSYCHOTROPIC DRUG.—The term ''psychotropic drug'' means a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is not a substance covered by section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) but is—

(A) used in the diagnosis, treatment, or prevention of a disease; and

(B) intended to have an altering effect on perception, emotion, or behavior.

(3) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(c) GAO STUDY AND REVIEW.—

(1) REVIEW.—The Comptroller General of the United States shall conduct a review of—

(A) the variation among States in definitions of psychotropic medications as used in regard to State jurisdiction over public education;

(B) the prescription rates of medications used in public schools to treat children diagnosed with attention deficit disorder, attention deficit hyperactivity disorder, and other disorders or illnesses;

(C) which medications used to treat such children in public schools are listed under the Controlled Substances Act; and

(D) which medications used to treat such children in public schools are not listed under the Controlled Substances Act, including the properties and effects of any such medications, including the incidence of hallucinations, psychosis, violence, suicide, heart problems, significant weight gain, or diabetes that students may experience while on these medications.

(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall prepare and submit a report that contains the results of the review under paragraph (1).

Mr. INHOFE. I do apologize to the managers of the bill as well as to the Chair. It was my understanding that I actually had that done previously. With that, if it is proper form now to get into the mix, I ask unanimous consent that I be permitted to speak as in morning business for up to 12 minutes.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The remarks of Mr. INHOFE pertaining to the introduction of S. 1269 are located in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. INHOFE. I thank the managers of this bill for giving me this time to make this presentation.

I yield the floor.

The PRESIDING OFFICER (Ms. CANTWELL). The Senator from New Hampshire.

Mr. GREGG. Madam President, I understand that I may go forward. I appreciate the courtesy of the Senator from Massachusetts.

AMENDMENT NO. 993

(Purpose: To provide for the regulation of Internet pharmacies)

Madam President, today we have been discussing, at some depth, and appropriately so, how to protect American citizens who purchase drugs overseas—from overseas pharmacies or from Canadian pharmacies—or purchase drugs on the Internet. This is a very significant issue for Americans, especially as more and more Americans use the Internet for the purposes of buying all sorts of items, including pharmaceuticals.

So we need to be sure this extraordinary regime we have set up in this country stays intact that allows a person, when he or she goes into an American drugstore or goes into an American supermarket, to be fairly confident the product they buy is not adulterated and the product they buy is what it says it is and that in the instance of a pharmaceutical or a medication, it is going to be what the doctor told them to take. That has been one of the great successes of American Government. It is because the Food and Drug Administration is overseeing this effort to protect the food supply and the pharmaceutical supply.

Whether the Food and Drug Administration has the wherewithal, the legal ability, and the technical and physical ability to protect an American who buys an overseas product, a medicine, and imports it into the United States is very much an issue. The FDA is very concerned about their capacity to police effectively drugs coming into this country, especially over the Internet.

So I have an amendment to this bill which basically is the Safe Internet Pharmaceutical Act, the purpose of which is to give the FDA the authority necessary to protect people who are buying pharmaceutical products over the Internet. This is, in my opinion, very important.

The importance of this has only been further stressed and exemplified by a warning that came out today, fortuitously, from the FDA on the issue of Internet pharmacies. I want to read extensively from this warning because it goes to the essence of the debate we have heard on the floor, especially from Senators supporting the proposal from the Senator from North Dakota relative to reimportation and safety and their representation that it is safe to buy over the Internet and that their amendment will make it legal to buy drugs from outside the United States over the Internet through their reimportation language.

This warning from the FDA states as follows: ''FDA Warns Consumers about Counterfeit Drugs from Multiple Internet Sellers.'' I am going to read quite a bit of the text because I think, first, it is so on point and it is so important:

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of—

I may not get all these medical terms correct, but I hope I do.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-LaRoche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

While this product is also used to help people lose weight and maintain that loss, it should not be used in certain patient populations and therefore is not a substitute for other weight loss products. In addition the drug interactions profile is different between Xenical and sibutramine, as is the dosing frequency; sibutramine is administered once daily while Xenical is dosed three times a day.

Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005.

Pictures of the counterfeit Xenical capsules can be seen on the Web site at FDA. I would note they look exactly like the Xenical that is legitimate. We had a Senator here earlier holding up two prescription bottles of, I think it was Lipitor, saying: These two bottles are exactly the same, and one could be bought in Canada for about a third of what it costs in the United States. Well, you can buy this Xenical over the Internet for probably about a third of what it costs in the United States. The only problem is it might kill you. I am going to read further:

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of 24 Web sites that appear on the pharmacycall365.com home page under the ''Our Websites'' heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online.

Then it lists the 24 Web sites, and some of them have very seductive

names: ''Pharmacea.org,'' ''MensHealthDrugs.net,'' ''MediClub.md''—very seductive names, in order to draw people into purchasing drugs on these sites.

Madam President, I ask unanimous consent that this press release from the FDA be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the FDA News, May 1, 2007]

FDA WARNS CONSUMERS ABOUT COUNTERFEIT DRUGS FROM MULTIPLE INTERNET SELLERS

The Food and Drug Administration (FDA) is cautioning U.S. consumers about dangers associated with buying prescription drugs over the Internet. This alert is being issued based on information the agency received showing that 24 apparently related Web sites may be involved in the distribution of counterfeit prescription drugs.

On three occasions during recent months, FDA received information that counterfeit versions of Xenical 120 mg capsules, a drug manufactured by Hoffmann-La Roche Inc. (Roche), were obtained by three consumers from two different Web sites. Xenical is an FDA-approved drug used to help obese individuals who meet certain weight and height requirements lose weight and maintain weight loss.

None of the capsules ordered off the Web sites contained orlistat, the active ingredient in authentic Xenical. In fact, laboratory analysis conducted by Roche and submitted to the FDA confirmed that one capsule contained sibutramine, which is the active ingredient in Meridia, an FDA-approved prescription drug manufactured by Abbott Laboratories.

While this product is also used to help people lose weight and maintain that loss, it should not be used in certain patient populations and therefore is not a substitute for other weight loss products. In addition the drug interactions profile is different between Xenical and sibutramine, as is the dosing frequency; sibutramine is administered once daily while Xenical is dosed three times a day.

Other samples of drug product obtained from two of the Internet orders were composed of only talc and starch. According to Roche, these two samples displayed a valid Roche lot number of B2306 and were labeled with an expiration date of April 2007. The correct expiration date for this lot number is actually March 2005. (Pictures of the counterfeit Xenical capsules provided by Roche can be viewed at http://www.fda.gov/bbs/topics/news/photos/xenical.html.)

Roche identified the two Web sites involved in this incident as brandpills.com and pillspharm.com. Further investigation by FDA disclosed that these Web sites are two of 24 Web sites that appear on the pharmacycall365.com home page under the ''Our Websites'' heading. Four of these Web sites previously have been identified by FDA's Office of Criminal Investigations as being associated with the distribution of counterfeit Tamiflu and counterfeit Cialis.

At this point, it appears that these Web sites are operated from outside of the United States. Consumers should be wary, if there is no way to contact the Web site pharmacy by phone, if prices are dramatically lower than the competition, or if no prescription from your doctor is required. As a result, FDA strongly cautions consumers about purchasing drugs from any of these Web sites which may be involved in the distribution of counterfeit drugs and reiterates previous public warnings about buying prescription drugs online [Consumers are urged to review the FDA Web page at www.fda.gov/buyonline/ for additional information prior to making purchases of prescription drugs over the Internet.]

The 24 Web sites appear on pharmacycall365.com: AllPills.net, Pharmacy–4U.net, DirectMedsMall.com, Brandpills.com, Emediline.com, RX-ed.com, RXePharm.com, Pharmacea.org, PillsPharm.com, MensHealthDrugs.net, BigXplus.net, MediClub.md, InterTab.de, Pillenpharm.com, Bigger-X.com, PillsLand.com, EZMEDZ.com, UnitedMedicals.com, Best-Medz.com, USAPillsrx.net, USAMedz.com, BluePills-Rx.com, Genericpharmacy.us and I-Kusui.jp.

Mr. GREGG. It is, of course, ironic that in the middle of this debate over how you make safe drugs that Americans are purchasing, and assure that the FDA has the proper oversight, that the FDA would be issuing this warning. It is a coincidence. The FDA did not do it because we are in the middle of this debate. They did it because they had received the necessary information to fairly well substantiate that at least in three incidents the medication that was purchased was not the medication that was approved by the FDA, even though it was represented as that medication, even though it came in a bottle that looked exactly like that medication, even though it had a tamperproof seal, and it had a label and a date as to when that medication would expire and a lot number. So it certainly looked legitimate. So this just confirms the concern which many of us have that we have to set up a regime where the FDA can properly review what is happening relative to drugs that are being purchased over the Internet, especially. It is not impossible to do that. In fact, it is very doable. That is why I will offer this amendment.

The amendment I will offer basically sets up a system whereby the FDA will require that pharmaceutical products sold over the Internet be subject to the jurisdiction of the United States and that they get an FDA seal of approval which is tamper-proof. So if a citizen wants to use a pharmaceutical site, he or she can go on line and call up a pharmaceutical site, such as drugs.com or whatever—that may actually be a site, so I probably shouldn't use that term—but a site where you think you can purchase drugs at a better price than what you are going to have to pay for them somewhere else, they will see on that Web site a seal like the Good Housekeeping Seal of Approval, only it will be a tamper-proof seal which will reflect the fact that the FDA monitors that site, monitors that pharmacy.

Also, the pharmacy has subjected itself to American jurisdiction, so that if there is an illegal act, they can be prosecuted, or if there are issues of liability, they can be sued; also, that there is contact information which is based in America relative to that and that there is a searchable database where you can go in and find out what that pharmacy has done in the past relative to its prescription-filling activity.

This would all be supported by a fee system which gives the FDA the resources to accomplish this type of monitoring. It really seems like the most logical thing to do.

There is no way you can stop the imagination and desire of the American people to get the best price. That is part of the essence of our character. So it is reasonable that Americans are going to use online pharmacies, but we have to make sure we have a system where we do not have one approval process for legitimate purchasing of drugs through pharmaceutical activity at your local pharmacy and then another process for purchasing drugs which has absolutely no oversight from the FDA if you purchase on the Internet. We have to make sure that if you are using an Internet site, the site has been subject to the same review as the local pharmacy down at the corner is subject to, relative to the quality and management of that pharmaceutical product they are selling. That is what this amendment does.

I hope no one will object to it, but I know other people will. But they shouldn't because this is really something whose time has come. So I am going to offer this amendment tonight. It is timely, of course, in light of this FDA warning which says there are potentially 24 Web sites they have identified, at least 3 of which are selling adulterated drugs, that they know of, which could seriously harm and possibly, if taken in the wrong dosage, since they aren't the proper drug, actually do more than just harm you, they could permanently injure you.

In light of that warning which came out today, it is totally reasonable and appropriate that the Congress should certainly, if it is going to do a drug safety bill relative to the FDA, include in it an Internet pharmacy safety regime which will give the American people some confidence that when they go on line to purchase a drug on line, the site, the portal they are purchasing it through, is subject to FDA review and the drug they are purchasing is an FDA-approved drug, which is made clear by having this tamper-proof seal of approval. It would also reflect the fact that the FDA actually has physical oversight over that pharmacy, that online pharmacy, and gives the FDA the resources to do that oversight. You can't just say: Go and do it, if they don't have the money to do it; you have to give them the resources to do it.

In addition, it sets up a one-stop shopping site at the FDA where people can go on line to the FDA site, check out that Internet pharmacy, if they wish, and make sure the Internet pharmacy does qualify and does carry FDA-approved drugs.

I think it is a very proper approach. It is something, as I mentioned, which is clearly timely in light of this FDA warning.

Madam President, at this time, I ask unanimous consent that the pending

amendment be set aside and that I may call up amendment No. 993 and ask for its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from New Hampshire [Mr. GREGG], for himself and Mr. COLEMAN, proposes an amendment numbered 993.

Mr. GREGG. I ask unanimous consent that the reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The amendment is printed in the RECORD of Tuesday, May 1, 2007, under ''Text of Amendments.'')

Mr. GREGG. I thank my colleagues for allowing me to go forward at this time.

Madam President, I yield the floor and make a point of order that a quorum is not present.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. MENENDEZ. Madam President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

AMENDMENT NO. 1010

Mr. MENENDEZ. Madam President, I rise today to talk about an issue of great importance but also of great concern: the importation of prescription drugs.

In their search for more affordable prescription drugs, many Americans have turned to pharmacies in other countries, either via the Internet or trips across the border. While I certainly understand their need for affordable drugs, I do have concerns about this particular solution. We must find a way to ensure that the drugs Americans are buying are safe.

I believe the Cochran amendment will do just that. Senator COCHRAN's amendment allows importation to take effect only if the Health and Human Services Secretary can ensure that it will pose no additional risk to the public health and result in a significant reduction in the cost of prescription drugs. So with this amendment, we get safe drugs at a reduced price, and our ultimate objective is achieved.

Looking closely at the issue of safety, I am also concerned about the importation of counterfeit drugs. Americans deserve to know the label on the bottle—we have seen colleagues put bottles up and show differences. Well, Americans deserve to know the label on the bottle matches the pills inside they are taking. The only way to ensure that is to provide strong protections. We have all heard horror stories about innocent Americans, starved for cheaper prescription drugs, going online or getting in their cars to go to foreign pharmacies to buy their medications. They are coming back home with what they think is their usual medication, but the reality might be quite different.

A recent New York Times article talked about the increasing number of counterfeit drugs. While in the past we may have noticed a misspelled label or off-color pill, today's counterfeit drugs are largely undetectable. The pills look correct, the cardboard boxes are the same, even the blister packaging and foil backing are all normal. But this is not your grandmother's forged medication. These are modern, scary, life-threatening tactics that place American lives in great danger.

While the supporters of the underlying amendment believe their proposal addresses some of these concerns, there are a number of safety concerns that I believe must be addressed by the Secretary of Health and Human Services, and that is why the Cochran amendment is so important.

The underlying proposal would undo current safety protections that ensure Americans are getting products that are essentially the same substance and quantity as what their doctor has prescribed.

While the proposal requires an importer to retain samples of products, it does not require that those be tested to ensure the drugs are the same as what the doctor ordered.

The proposal does not require that imported drugs be approved in their country of origin. It relies only on a paper trail to enforce chain-of-custody requirements, leaving consumers susceptible to unscrupulous dealers who can simply forge documents or copy anticounterfeit technology.

While supporters of the proposal claim that they give FDA the authority to conduct inspections of foreign manufacturing plants, the reality is that the United States would actually have to get permission for those inspections from foreign countries, and that is assuming we can even trace the purchase of those products to their country of origin in the first place.

Importers are not required to disclose the origin of the products they sell, so consumers would have no way to opt out if they wanted to ensure they were getting Food and Drug Administration-approved products.

Finally, the underlying amendment allows importation from far more than just Canada. Written into the proposal is permission to import from Canada and other countries, including certain countries in the EU, even if the drugs leave the chain of custody of the manufacturer or fall outside of the Food and Drug Administration's jurisdiction. Because of the EU structure, we would actually be opening ourselves to drugs from countries such as Latvia, Estonia, and other recent additions to the EU. Some of these countries from the former Soviet Union have counterfeit rates up to 20 percent.

The Cochran amendment would ensure these safety concerns are resolved and that the Government provides for the protection of the public's health and safety.

Now, in my mind, as we have this debate, the real problem is affordability of prescription drugs, and the real solution to that problem is expanding access to affordable drugs in the United States. In that effort, I take a back seat to no one. But at the same time, I strongly believe we must also protect the health and safety of those we represent.

These two goals are not mutually exclusive. We can and must do both. I believe this amendment—the Cochran amendment—accomplishes what we all want, which is expanding access to safe, affordable drugs. I encourage my colleagues to support the Cochran amendment.

AMENDMENT NO. 1011

Mr. KOHL. Madam President, I rise today to join Senators STABENOW, LOTT, BROWN, and THUNE in offering amendment No. 1011. This amendment will help speed the introduction of cost-saving generic drugs by preventing abuses of the Food and Drug Administration citizen petition process.

Consumers continue to suffer all across our country from the high—and ever rising—cost of prescription drugs. A recent independent study found that prescription drug spending has more than quadrupled since 1990, and now accounts for 11 percent of all health care spending. At the same time, the pharmaceutical industry is one of the most profitable industries in the world, returning more than 15 percent on their investments.

One key method to bring prescription drug prices down is to promote the introduction of generic alternatives to expensive brand name drugs. Consumers realize substantial savings once generic drugs enter the market. Generic drugs cost on average of 63 percent less than their brandname equivalents. One study estimates that every 1 percent increase in the use of generic drugs could save as much as $4 billion in health care costs.

This is why I have been so active in pursuing legislation designed to combat practices which impede the introduction of generic drugs. The amendment offered today, includes provisions based on legislation that I first introduced with Senator LEAHY in the last Congress, and targets one particularly pernicious practice by brandname drug companies to impede or block the marketing of generic drugs—abuse of the FDA citizen petition process.

FDA rules permit any person to file a so-called citizen petition to raise concerns about the safety or efficacy of a generic drug that a manufacturer is seeking FDA approval to bring to market. While this citizen petition process was put in place for a laudable purpose, unfortunately in recent years it has been abused by frivolous petitions submitted by brandname drug manufacturers, or individuals acting at their behest, whose only purpose is to delay the introduction of generic competition. The FDA has a policy of not granting any new generic manufacturer's drug application until after it has

considered and evaluated any citizen petitions regarding that drug. The process of resolving a citizen petition, even if ultimately found to be groundless, can delay the approval by months or years. Indeed, brandname drug manufacturers often wait to file citizen petitions until just before the FDA is about to grant the application to market the new generic drug manufacturer's solely for the purpose of delaying the introduction of the generic competitor for the maximum amount of time possible. This gaming of the system should not be tolerated.

In recent years, FDA officials have expressed serious concerns about the abuse of the citizen petition process. In 2005, FDA Chief Counsel Sheldon Bradshaw noted that ''[t]he citizen petition process is in some cases being abused. Sometimes, stakeholders try to use this mechanism to unnecessarily delay approval of a competitor's products.'' He added that he found it ''particularly troublesome'' that he had ''seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to take the time to consider the arguments raised in the petition, regardless of their merits, and regardless of whether the petitioner could have made those very arguments months and months before.''

And a simple look at the statistics gives credence to these concerns. Of the 21 citizen petitions for which the FDA has reached a decision since 2003, 20—or 95 percent of them—have been found to be without merit. Of these, 10 were identified as ''eleventh hour petitions''—defined as those filed less than 6 months prior to the estimated entry date of the generic drug. None of these 10 ''eleventh hour petitions'' were found to have merit, but each caused unnecessary delays in the marketing of the generic drug by months or over a year, causing consumers to spend millions and millions of dollars for their prescription drugs than they would have spent without these abusive filings.

Among other things, our amendment will, for the first time, require all those who file citizen petitions to affirm certain basic facts about the truthfulness and good faith of the petition, similar to what is required of every litigant who makes a filing in court. Our amendment also includes a provision from my bill that directs the HHS that all citizen petitions on generic drug applications be adjudicated within 6 months of filing, which will put an end to excessive delays in bringing needed generic drugs to market because of the filings of these petitions.

While I strongly support this amendment and I am pleased that many of my provisions were included, I do wish the amendment could have gone even farther and include my provision to allow the Department of Health and Human Services—the FDA's parent agency—the power to sanction those who abuse the process. While this proposal would not have an effect on any person filing a truly meritorious citizen petition, this provision would serve as a strong deterrent to attempts by brand name drug manufacturers or any other party that seeks to abuse the citizen petition process to thwart competition. Having said that, I do believe our amendment today is an important step in the right direction to remove a significant obstacle exploited by brand name drug companies to prevent or delay the introduction of generic drugs. I urge my colleagues to support this amendment.

AMENDMENT NO. 1016

Mr. SPECTER. Madam President, the Food and Drug Administration Revitalization Act is an important step toward protecting American consumers and patients and ensuring the safety of prescription drugs. To increase the safety and efficacy of prescription drug approval, I will offer an amendment to establish the National Centers of Pharmaceutical Innovation. These Centers, in consultation with the Food and Drug Administration, FDA, Commissioner, will modernize medical product development and enhance product safety.

I am very concerned about long delays and the safety of bringing new drugs to patients. The FDA has been faced with the withdrawal of prescription drugs from the market due to concerns about increased health risks. This situation illustrates the difficulty in achieving the right balance in investigating new drugs that, while intended to help patients, can also come with very serious risks. Furthermore, such incidents could lead to the erosion of public confidence in the safety of medicines developed by drug companies. Drug companies spend enormous sums of money to test potential new candidate medicines. Not only is the process of developing and testing a new drug costly, it is lengthy as well. As a result of delays in the clinical trials process, there are fewer drug discoveries each passing year, ultimately hindering our Nation's competitiveness in this field.

According to Ernst R. Berndt, Ph.D., Adrian H. B. Gottschalk, S.M., Matthew W. Strobeck, Ph.D., Massachusetts Institute of Technology, MIT, Sloan School of Management, ''scientific advances and enhanced [research and development] efforts, the number of average annual new drug applications, NDAs, and new biologic license applications, BLAs, approved by the U.S. Food and Drug Administration has been smaller after 2000 than in the mid-1990s. Moreover, recent estimates suggest the average costs of bringing a new medicine to market have increased sharply to between $800 million and $1.7 billion, with the lower estimate being 2½ times higher than similar inflation-adjusted estimates published a dozen years earlier.'' Clearly, there is great need to improve the methods and science that are used to approve prescription drugs.

I am further concerned that new technologies, including genomics, proteomics, and bioinformatics are not being fully incorporated into the drug approval process. Using these new technologies as part of the clinical drug approval process has the potential to substantially reduce costs and the time needed to develop and test new drugs. Additionally, we must improve the workforce available to pharmaceutical companies, which is not well trained in the modern tools needed for sophisticated drug development. The FDA does not have a structured research program to bridge this knowledge and workforce gap and has few extramural research activities in place to tap the expertise available in our Nation's university health programs.

This amendment will establish the National Centers for Pharmaceutical Innovation to improve the development and testing of new drugs so that they make it to market more quickly and remain there. Up to five centers will be operated by universities in partnership with the FDA to develop methods to utilize new technology to improve the drug approval system. They will also expand the quality and number of professionals trained to work in this field. The centers will introduce new technologies to improve the manufacture of pharmaceutical and biotechnology products.

I believe these centers can provide a significant part of the solution to this complex problem. These centers will be established from qualified universities that have graduate training programs with extensive experience in the development and evaluation of medicines; and proficiencies in pharmaceutical and biotechnology science and engineering. It is the expectation that the work completed by these centers and the FDA would lead to an increased number of drugs brought to market by industry, at a decreased cost. Another effect will be an enormous gain to the public's health, while decreasing the chance of unintentional harm and costs of medical care.

The National Centers for Pharmaceutical Innovation hold a promising solution to the problems in drug discovery and safety facing our Nation today. I encourage my colleagues to support this important amendment.

OVERTURNING DSHEA

Mr. HATCH. My office has been inundated by calls from people throughout the country who believe that this legislation, specifically the provision establishing a Reagan-Udall Institute, will overturn the Dietary Supplement Health and Education Act of 1994. That has not been my reading of the bill, but I wonder if other Senators have heard similar concerns?

Mr. HARKIN. Yes, I have received a good many calls as well. And, I have to say that I would be very concerned, as I know the Senator from Utah is, if

Mr. HARKIN. Yes, I have received a good many calls as well. And, I have to say that I would be very concerned, as I know the Senator from Utah is, if anything in the bill we are considering, S. 1082, would overturn DSHEA, a law we fought side-by-side to see enacted.

Mr. ENZI. It might be helpful if I explained the provision you are discussing, as my office has received many calls as well and I believe the callers are not informed about this matter. Subtitle B of title II of S. 1028 establishes the Reagan-Udall Foundation for the Food and Drug Administration. That simple purpose of that nonprofit Foundation is to lead collaborations among the FDA, academic research institutions and industry designed to bolster research and development productivity, provide new tools for improving safety in regulated product evaluation, and in the long term make the development of those products more predictable and manageable.

Mr. KENNEDY. That is exactly the purpose of the Foundation, which was included in the drug safety legislation Senator ENZI and I introduced last year. The Foundation will be financially supported by industry and philanthropic donated funds. A chief scientist at FDA will promote intramural research and coordinate it with efforts at the Foundation.

Mr. HATCH. That explanation is very helpful. What, specifically, would the role of the Foundation be with respect to dietary supplements?

Mr. KENNEDY. Let me make absolutely clear that the Reagan-Udall Foundation will in no way override, overturn or conflict with the Dietary Supplement Health and Education Act. Nothing in this bill would have that effect.

Mr. ENZI. Yes, we took great pains to make certain there would be no conflict with DSHEA. Regarding foods, and dietary supplements are generally regulated as foods, the general directive of the Foundation is to identify holes in the evaluation of food safety and identify ways to address those deficiencies through collaborative research with industry.

Mr. HARKIN. So to make this absolutely clear, what you are saying is that the bill we are debating would in no way interfere with consumers' access to dietary supplements?

Mr. HATCH. To add to that point, it seems that the language could, in fact, help dietary supplement consumers, because it would allow collaboration between government and industry to conduct research on issues that might be helpful to supplement consumers?

Mr. KENNEDY. Yes, that is the case.

Mr. ENZI. I agree with Chairman KENNEDY's assessment.

Mr. HATCH. I thank you for those assurances and that clarification.

Mr. HARKIN. This has been a very helpful discussion, because Senator HATCH and I could never support legislation that would interfere with DSHEA and we are glad to receive the assurances of the chairman and the ranking Republican on the committee.

MORNING BUSINESS

Mr. MENENDEZ. Madam President, I ask unanimous consent that there now be a period of morning business with Senators permitted to speak therein for up to 10 minutes each.

The PRESIDING OFFICER. Without objection, it is so ordered.

DEPARTMENT OF JUSTICE

Mr. LEAHY. Madam President, when I was a young law student at Georgetown, the event that stands out the most in my memory was a morning that I and a few other young law students working at various agencies for the summer had with the then Attorney General. It was Attorney General Robert Kennedy. In that meeting, he stressed to us over and over again the professionalism of the Department of Justice and how the professionals had to stay out of any kind of partisan politics and that he would insist upon it.

I was inspired by that meeting. I think it probably shaped my decision to go into public life more than any other single meeting I had.

I ask unanimous consent that an article in today's USA Today by Ronald Goldfarb entitled ''Crossing the Line at Justice'' be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From USA Today, Wednesday, May 2, 2007]

CROSSING A LINE AT JUSTICE

(By Ronald Goldfarb)

The current agonies of Attorney General Alberto Gonzales call to mind a dramatic moment in the Robert F. Kennedy Justice Department. Members of his organized crime section were in RFK's office reviewing our pending investigations and cases. One of our group advised Kennedy that his grand jury investigations were about to lead to the indictment of the then-mayor of a large Midwestern city, one that had voted for his brother John Kennedy in the close presidential election of 1960.

When my colleague completed his report about the big scalp about to be added to our list of political corruption cases, RFK was quiet. It happened that the scalp in question belonged to President Kennedy's ambassador-designate to Greece. The attorney general smiled slightly and facetiously remarked: ''Well, that's nice. Now my brother's going to have to put me on the Supreme Court.'' The indictment went forward and included others in the city's political (Democratic) machine. All were convicted.

That anecdote is relevant today as the Senate Judiciary Committee considers the attorney general's recent dismissals of several U.S. attorneys. When it comes to the proper administration of justice in the Department of Justice, there are politics and there are politics.

THE TWO P'S

Capital ''P'' politics—that is, party politics, such as the partisan personal shenanigans of Gonzales meddling with the independence of competent prosecutors' discretion in response to political pressures—are improper and have no place in the justice system. Small ''p'' politics, the imposition of discretionary preferences, policies and priorities in the focus of prosecutorial discretion, generally are proper. Partisans must accept them, like it or not. They are not the basis for replacing attorneys general.

The distinction is important. When the Justice Department that I served in during the Kennedy administration came to office, ''political'' priorities changed. The internal security division, active and robust during the Eisenhower administration when loyalty was a major concern, was de-emphasized and eventually was deactivated. The organized crime and the civil rights sections, small and quiet in earlier years, grew into major centers of departmental work and were the centerpiece of RFK's regime. That kind of priority setting is proper.

Administrations come to office offering change. Like these changes or not, people cannot claim they involve improper politics. Critics have the right to change administrations with their votes in subsequent elections. Had Al Gore been elected, no doubt environmental prosecutions would have taken front and center in the department's efforts.

After Sept. 11, 2001, homeland security would have been any attorney general's special interest, RFK's included. So if one deplores the values and priorities of the John Ashcroft and Gonzales administrations at Justice, USA Patriot Act excesses and the like, the recourse will be at the 2008 voting machines.

On the other hand, capital ''P'' party politics have no place in any Justice Department. That is the unique indictment of Gonzales, and one that should lead to his replacement. All attorneys general face political pressure to act against their parties' political enemies and to protect their friends. Those are the moments of truth for all attorneys general, the one that Gonzales failed, to the embarrassment of even his own party representatives.

RFK'S TESTS

When RFK was attorney general, two comparable moments stand out in my memory. In one, his notorious father's long-time attorney—James Landis, ''a virtual member of the immediate family,'' according to one biography—was charged with failing to file his tax returns for five years. Immense pressures were put on Kennedy to find an excuse not to indict the aging and prestigious former Harvard law dean. RFK stayed out of the decision-making process, and Landis pleaded guilty and received a brief incarceration. But for his close association with the Kennedys, Landis probably would not have suffered so. Everyone wanted to help Landis, but they were super self-conscious about the propriety of doing so.

A similar moment arose when an investigation showed that the brother of the influential congressman from New York, Eugene Keogh, had abused his office as a New York state supreme court judge. Kennedy agonized over the political pressures on him; he worried that the not open-and-shut case might not be winnable, after major political embarrassment to Kennedy loyalists. To his credit, Keogh told Kennedy he knew he'd do the right and fair thing. The attorney general's aides pressed him to do what he'd do in any other non-political case. Judge J. Vincent Keogh was indicted and convicted. That is the only way an attorney general can keep the balance of justice even and credible.

Gonzales needed aides who spoke to him with comparable candor and rectitude. Instead, he is falling on his sword over the U.S. attorney firings that he administered without knowing, as he has testified, much about them at the time. Like former vice presidential aide Lewis ''Scooter'' Libby in the

Valerie Plame leak case, others set the political process in motion, and the loyal aide did the deed and took the rap. The Senate should not stop at Gonzales' actions, but should press to find out who pressured him to take these unconscionable actions.

Ashcroft supermoralistically draped the body of the department's statue of justice to hide her contours; Gonzales amoralistically tore off her blindfold. Both diminished the prestige of an important government agency.

TRIBUTE TO COLONEL ANTHONY J. ''LAZER'' LAZARSKI

Mr. INHOFE. Madam President, I am here today to recognize and pay tribute to COL Anthony J. ''Lazer'' Lazarski, Chief of the Air Force Senate Liaison, for his 25 years of exceptional service and dedication to the U.S. Air Force and our great country. Colonel Lazarski is a command pilot with over 2,300 flight hours in 12 different types of aircraft, including the RF–4, F–15, F–16, F–111 and F–117. He has supported combat operations around the world, to include the Libya Raid and Operations Desert Storm, Desert Fox, Allied Force, Southern Watch, and Iraqi Freedom. Throughout his military career, he has been recognized by his superiors and subordinates as a leader in the air and on the ground—an Airman with the ability to motivate and lead.

COL Lazer Lazarski grew up in North Arlington, NJ, and watched them build the Twin Towers of the World Trade Center from the basement up. He earned an appointment to the Air Force Academy and graduated in 1982 with military honors. Upon completion of pilot training, he was selected to fly the F–111 and earned the distinction of Top Gun for both his T–38 Introduction to Fighter Fundamentals class and his F–111 Replacement Training Unit class. While flying in Tactical Air Command with the 79th NATO Tigers at RAF Upper Heyford, he was selected as the wing's youngest instructor pilot. Shortly thereafter, he was selected as the youngest United States Air Forces in Europe flight examiner. As a pilot, I can attest to the fact that you only allow your sharpest and most mature pilots to set, evaluate, and enforce the standards for other pilots. I happen to be a flight instructor currently. I can assure you, they are the very best people. This is a major accomplishment he was able to achieve.

Colonel Lazarski later transitioned to the F–117 Stealth Fighter and earned Top Gun in his third aircraft, this time during a Southern Watch deployment over the skies of Iraq. Colonel Lazarski demonstrated he could not only deliver precise weapons on target on time, he could also motivate and lead others. In recognition of his extraordinary leadership, he was named 12th Air Force Flight Commander of the Year, and selected to attend the Naval War College.

After graduating from the Naval War College in 1994, he served 3 years in Naples, Italy at NATO Headquarters, including as the aide-de-camp to two different Commanders, Allied Air Forces in Southern Europe. One of these Commanders was then LTG Mike Ryan, who would later become Air Force Chief of Staff. During his tour, he was one of the first combat troops on the ground in Sarajevo as he helped set up the NATO Air Operations Center.

In 1997, he transitioned to the F–15 Strike Eagle, serving as the 336th Fighter Squadron Assistant Operations Officer and deployed commander from Seymour Johnson Air Force Base, NC. During this tour he also served as Chief of the Command Post and integrated new command and control systems to include hurricane tracking/forecasting systems put to test in 3 years of multiple hurricanes.

In 2001 he graduated No. 1 from his Air War College Class, earning the Wright Brothers Officership Award and Military Outstanding Volunteer Medal. This honor earned him the right to serve the next year at Vance Air Force Base, in my home state of Oklahoma as the Deputy Operations Group Commander.

Due to the superb leadership Colonel Lazarski demonstrated at Vance, he was selected as the Director of Air Combat Command's Commander Action Group—the strategic ''think tank'' for our Air Force's lead combat command. In this position he was given the immense responsibility for developing strategy, doctrine, concepts, tactics and procedures for U.S. air and space power employment.

Colonel Lazarski's next assignment led him back to command, this time in Air Education Training Command as the Commander of the 479th Flying Training Group where he was responsible for training new pilots in the T–6, and new fighter pilots and weapons officers in the T–38. Colonel Lazarski oversaw 115 aircraft averaging 300 sorties a day, and despite five hurricanes in one season, no student ever graduated late under Colonel Lazarski's leadership.

In 2005 at the culmination of an exceptional military career, Colonel Lazarski was reassigned to Capitol Hill as the Chief of the Air Force Senate Liaison Division. Here Colonel Lazarski integrated his remarkable experience and leadership with ceaseless integrity, initiative, and persistence to result in unparalleled effectiveness on behalf of the Air Force and our Nation.

We offer our sincere thanks to Colonel Lazarski, his wife Stephanie, and their son Andrew for their unwavering support of our country and the freedom we hold so dear. We congratulate Colonel Lazarski on the completion of an exemplary active-duty career. Utilizing the theme from one of my favorite books, Message to Garcia, let me close by saying: Message delivered and job well done! Now a new mission awaits you, and I'm honored to have you serve your country again, this time as my Military Legislative Assistant. Congratulations and welcome!

REMOVAL OF COSPONSOR

Mr. CORNYN. Madam President, I ask that Senator PETE DOMENICI be removed as a cosponsor to S. 1038, the Workforce Health Improvement Act, and added as a cosponsor to S. 1083, the SKIL Act. Let the RECORD reflect that due to a clerical error Senator DOMENICI was inadvertently added as a cosponsor to the Wokforce Health Improvement Act.

IN RECOGNITION OF HEIDEH SHAHMORADI

Mr. BOND. Madam President, today I rise to acknowledge the very special and meaningful contributions of Ms. Heideh Shahmoradi, who is departing the U.S. Senate after serving as detailee for some 4 years from the Department of Transportation. I come to the floor today to thank personally Heideh for her assistance and professionalism as a detailee to me on both the Environment and Public Works, EPW, Committee and the Appropriations Committee.

In my former position as chair of the EPW's Subcommittee on Transportation and Infrastructure, Heideh provided me with invaluable advice and help in the development and passage of the highway reauthorization legislation, Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users: or SAFETEA. Heideh played a key role in helping the committee understand the complexities and implications of SAFETEA which helped to ensure that the final legislation properly balanced these very complex policy and funding issues. And as a program expert from the Department, Heideh was able to provide valuable insights on the potential impact of the legislation on highway transportation activities. Heideh not only contributed significantly in analyzing the legislation but she also performed important duties, such as research, fact-checking, editing, and drafting report language and legislation. Heideh did it all with distinction and unflappable good humor.

Her skills and performance on working on the EPW Committee made it an easy decision to bring her back from the Department to help me on the Appropriations Committee. Heideh not only continued to assist me on the Federal-aid highway programs on the Senate Transportation, HUD, and Related Agencies Appropriations Subcommittee, but she also quickly became a resource and expert on all of the other modes under the Department of Transportation.

Throughout her tenure on Capitol Hill, Heideh provided technical expertise and programmatic knowledge that was critical in policymaking decisions on both the authorizing and appropriations committees. Her ability to provide a reality check on legislation helped tremendously in protecting the best interests of our communities and

taxpayers. She is simply a true professional civil servant that we are fortunate to have in government.

Finally, Heideh is a quick study, adaptable, very good at working with others, and cool under pressure. She also is a person of absolute integrity, honor, and loyalty. To their credit, the leadership at the Department of Transportation has recognized her accomplishments and skills and will be giving her new challenges and opportunities. Her departure is a great loss to the Appropriations Committee and to my office in particular. She will be missed. I strongly commend Heideh for her service to me and the U.S. Senate and, while she is leaving us, she will always be part of the Bond office team. I personally wish Heideh, her husband Torrance, and her son Corey all the best.

ADDITIONAL STATEMENTS

HONORING KENT ''OZ'' C. NELSON

• Mr. ISAKSON. Madam President, today I wish to acknowledge a very special occasion. It has come to my attention that on May 9, the Centers for Disease Control and Prevention and the CDC Foundation in Atlanta will be honoring Kent ''Oz'' C. Nelson, retired chair and CEO of UPS, for his unselfish and untiring work on behalf of CDC and public health around the globe. They will be dedicating CDC's main auditorium as the Kent ''Oz'' C. Nelson Auditorium. This is a great honor for a man who truly deserves it.

As elected officials, we naturally and rightfully expect to hear from interested constituents and from the leaders of our governmental institutions about programmatic and capital needs. It is much more unusual to hear about such needs from a CEO-level leader of a global corporation like UPS. But over the past 8 years, Oz and many other CEO's like him, including Bernie Marcus, Phil Jacobs and Christine Jacobs, have regularly written, called and visited Washington, DC to remind us of the importance of upgrading CDC's Atlanta-based labs and facilities to ensure that the world's best scientists are equipped with world-class facilities to support their work.

During a tour of CDC in the fall of 1999, Oz, Bernie and Phil were troubled by the condition of CDC labs and its negative impact on CDC's ability to recruit top scientists and to protect all Americans from a host of threats ranging from SARS, anthrax and pandemic flu to obesity and environmental toxins. Scientists were working in overcrowded World War II Quonset huts and cinder block labs with frayed wiring and poor ventilation.

Oz could have just written a letter. He could have written off CDC's problems as the government's problem. Instead, he helped organize a concerted effort to highlight the problem and encourage a solution. In the last 8 years, Congress has appropriated $1.2 billion of the $1.6 billion needed to complete CDC's master facilities plan. One needs only tour CDC's campus and visit with the scientists there to see the amazing results.

As elected officials, we learn early to appreciate people like Oz Nelson. People who are never too busy to care, never to busy to identify and help solve problems. Since ''retiring,'' and I use that term loosely in Oz's case, he has chaired the Annie Casey Foundation, served on the board of the Carter Center in Atlanta, served on the board of the United Way of America and chaired its national fundraising campaign, chaired the board of the CDC Foundation and been instrumental in starting and supporting an Atlanta-based Museum of Patriotism that celebrates the American spirit. And these are just a few of his many nonprofit interests.

Oz Nelson is, himself, a patriot who embodies the very best of the American spirit. And I know those of you who know and have worked with Oz join me today in congratulating him on the dedication of the new Kent ''Oz'' C. Nelson Auditorium at CDC.•

MESSAGES FROM THE HOUSE

At 12:03 p.m., a message from the House of Representatives, delivered by Ms. Niland, one of its reading clerks, announced that the House has agreed to the following concurrent resolutions:

H. Con. Res. 95. Concurrent resolution honoring the career and research accomplishments of Frances E. Allen, the 2006 recipient of the A.M. Turing Award.

H. Con. Res. 112. Concurrent resolution supporting the goals and ideas of a National Child Care Worthy Wage Day.

H. Con. Res. 118. Concurrent resolution congratulating the City of Chicago for being chosen to represent the United States in the international competition to host the 2016 Olympic and Paralympic Games, and encouraging the International Olympic Committee to select Chicago as the site of the 2016 Olympic and Paralympic Games.

At 3:01 p.m., a message from the House of Representatives, delivered by Ms. Niland, one of its reading clerks, announced that the House having proceeded to reconsider the bill (H.R. 1591) making emergency supplemental appropriations for the fiscal year ending September 30, 2007, and for other purposes, returned by the President of the United States with his objections, to the House of Representatives, in which it originated, it was resolved that the said bill do not pass, two-thirds of the House of Representatives not agreeing to pass the same.

MEASURES REFERRED

The following concurrent resolutions were read, and referred as indicated:

H. Con. Res. 95. Concurrent resolution honoring the career and research accomplishments of Frances E. Allen, the 2006 recipient of the A.M. Turing Award; to the Committee on the Judiciary.

H. Con. Res. 112. Concurrent resolution supporting the goals and ideas of a National Child Care Worthy Wage Day; to the Committee on Health, Education, Labor, and Pensions.

MEASURES PLACED ON THE CALENDAR

The following concurrent resolution was read, and placed on the calendar:

H. Con. Res. 118. Concurrent resolution congratulating the City of Chicago for being chosen to represent the United States in the international competition to host the 2016 Olympic and Paralympic Games, and encouraging the International Olympic Committee to select Chicago as the site of the 2016 Olympic and Paralympic Games.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred as indicated:

EC–1711. A communication from the Under Secretary of Defense (Comptroller), transmitting, pursuant to law, the report of a violation of the Antideficiency Act by the Department of the Army, case number 05-09; to the Committee on Appropriations.

EC–1712. A communication from the Under Secretary of Defense (Comptroller), transmitting, pursuant to law, a report entitled ''Acceptance of Contributions for Defense Programs, Projects, and Activities; Defense Cooperation Account''; to the Committee on Armed Services.

EC–1713. A communication from the Principal Deputy, Office of the Under Secretary of Defense (Personnel and Readiness), transmitting, the report of (7) officers authorized to wear the insignia of the grade of major general in accordance with title 10, United States Code, section 777; to the Committee on Armed Services.

EC–1714. A communication from the Chairman and President, Export-Import Bank of the United States, transmitting, pursuant to law, a report relative to a transaction involving exports to Ghana; to the Committee on Banking, Housing, and Urban Affairs.

EC–1715. A communication from the Assistant Administrator for Procurement, Contract Management Division, National Aeronautics and Space Administration, transmitting, pursuant to law, the report of a rule entitled ''NASA Implementation of OMB Guidance on Nonprocurement Debarment and Suspension'' (RIN2700-AD32) received on April 27, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1716. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Implementation of Section 621(a)(1) of the Cable Communications Policy Act of 1984 as amended by the Cable Television Consumer Protection and Competition Act of 1992'' ((FCC 06-180)(MM Docket No. 05-311)) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1717. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Milano, Texas'' (MB Docket No. 05-97) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1718. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to

law, the report of a rule entitled ''Implementation of Section 629 of the Consolidated Appropriations Act, 2004'' (FCC 06-117) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1719. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Roma, Texas'' (MB Docket No. 05-142) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1720. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Ashland, Greensburg, and Kinsley, Kansas; and Alva, Medford, and Mustang, Oklahoma'' (MB Docket No. 06-65) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1721. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Wofford Heights, California'' (MB Docket No. 03-91) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1722. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Glen Arbor, Michigan'' (MB Docket No. 03-142) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1723. A communication from the Chief of Staff, Media Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Amendment of Section 73.202(b), Table of Allotments, FM Broadcast Stations, Jackson, Wyoming'' (MB Docket No. 05-101) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1724. A communication from the Deputy Bureau Chief, Consumer and Governmental Affairs Bureau, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Rules and Regulations Implementing Minimum Customer Account Record Exchange Obligations on All Local and Interexchange Carriers'' ((FCC 06-134)(CG Doc. 02-386)) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1725. A communication from the Management Analyst, Office of the Managing Director, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''In the Matter of Amendment of the Schedule of Application Fees Set Forth in Sections 1 .1102 through 1.1107 of the Commission's Rules'' ((GEN Docket No. 86-285)(FCC 06-131)) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1726. A communication from the Acting Legal Advisor, Mobility Division, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Implementation of Section 309(j) and 337 of the Communications Act of 1934 as Amended; Promotion of Spectrum Efficient Technologies on Certain Part 90 Frequencies'' ((FCC 07-39)(WT Docket No. 99-87)) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1727. A communication from the Chief, Policy and Rules Division, Federal Communications Commission, transmitting, pursuant to law, the report of a rule entitled ''Revision of Parts 2 and 15 of the Commission's Rules to Permit Unlicensed National Information Infrastructure Devices in the 5 GHz Band'' ((FCC 06-96)(ET Docket No. 03-122)) received on April 30, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1728. A communication from the Chairman, Surface Transportation Board, Department of Transportation, transmitting, pursuant to law, the report of a rule entitled ''Regulations Governing Fees for Services Performed in Connection with Licensing and Related Services—2007 Update'' (STB Ex Parte No. 542) received on April 27, 2007; to the Committee on Commerce, Science, and Transportation.

EC–1729. A communication from the Deputy Assistant Secretary for Land and Minerals Management, Department of the Interior, transmitting, pursuant to law, the report of a rule entitled ''Geothermal Valuation'' (RIN1010-AD32) received on April 26, 2007; to the Committee on Energy and Natural Resources.

EC–1730. A communication from the Director, Minerals Management Service, Department of the Interior, transmitting, pursuant to law, a report relative to the Department's proposed final 5-Year Outer Continental Shelf Oil and Gas Leasing Program for years 2007-2012; to the Committee on Energy and Natural Resources.

EC–1731. A communication from the Chief of the Publications and Regulations Branch, Internal Revenue Service, Department of the Treasury, transmitting, pursuant to law, the report of a rule entitled ''LMSB Tier II Issue - Field Directive on the Examination of IRC Section 165 Casualty Losses No. 1'' (LMSB-04-0407-030) received on April 30, 2007; to the Committee on Finance.

EC–1732. A communication from the Assistant Secretary, Office of Legislative Affairs, Department of State, transmitting, pursuant to law , the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment abroad and the export of defense articles or defense services in the amount of $100,000,000 or more to Japan; to the Committee on Foreign Relations.

EC–1733. A communication from the Assistant Secretary, Office of Legislative Affairs, Department of State, transmitting, pursuant to law , the certification of a proposed manufacturing license agreement for the manufacture of significant military equipment in Germany; to the Committee on Foreign Relations.

EC–1734. A communication from the Interim Director, Pension Benefit Guaranty Corporation, transmitting, pursuant to law, the report of a rule entitled ''Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits'' (29 CFR Parts 4022 and 4044) received on April 30, 2007; to the Committee on Health, Education, Labor, and Pensions.

EC–1735. A communication from the Secretary of Labor, transmitting, the report of proposed legislation entitled ''Child Labor Protection Act of 2007''; to the Committee on Health, Education, Labor, and Pensions.

EC–1736. A communication from the Chairman, U.S. International Trade Commission, transmitting, pursuant to law, the Commission's Semiannual Report for the period October 1, 2006 through March 31, 2007; to the Committee on Homeland Security and Governmental Affairs.

EC–1737. A communication from the Assistant Secretary for Legislative Affairs, Department of Homeland Security, transmitting, pursuant to law, a report relative to the Security Plan for Essential Air Service and Small Community Service Airports; to the Committee on Homeland Security and Governmental Affairs.

EC–1738. A communication from the Secretary of Health and Human Services, transmitting, pursuant to law, a report relative to the impact and effectiveness of Administration for Native Americans Projects during fiscal year 2005; to the Committee on Indian Affairs.

EC–1739. A communication from the Assistant Secretary for Indian Affairs, Department of the Interior, transmitting, the report of draft legislation intended to ''provide for the use and distribution of the funds awarded to the Minnesota Chippewa Tribe, et al., by the United States Court of Federal Claims in Docket Nos. 19 and 188, and for other purposes''; to the Committee on Indian Affairs.

EC–1740. A communication from the Chief Justice of the Supreme Court of the United States, transmitting, pursuant to law, an amendment to the Federal Rules of Appellate Procedure that has been adopted by the Supreme Court; to the Committee on the Judiciary.

EC–1741. A communication from the Deputy General Counsel, Office of Financial Assistance, Small Business Administration, transmitting, pursuant to law, the report of a rule entitled ''Liquidation and Debt Collection Activities'' (RIN3245-AE83) received on April 30, 2007; to the Committee on Small Business and Entrepreneurship.

PETITIONS AND MEMORIALS

The following petitions and memorials were laid before the Senate and were referred or ordered to lie on the table as indicated:

POM–77. A joint resolution adopted by the Legislature of the State of Idaho urging Congress to support Federal legislation transferring management of National Forest System Lands within Idaho to the State of Idaho to be managed for the benefit of the rural counties and schools; to the Committee on Energy and Natural Resources.

HOUSE JOINT MEMORIAL NO. 21

Whereas, the United States Forest Service administers the management of 39 percent of the land base in the state of Idaho, and an additional 22 percent is administered by the United States Bureau of Land Management; and

Whereas, pursuant to 16 U.S.C. Section 471, an 1891 law authorizing the President to establish national forests, the purpose for establishing and administering national forests was to set aside public lands reserved as national forests to be controlled and administered, to the extent practical, in accordance with the Act which provided that ''no national forest may be established except to improve and protect the forest, or to secure favorable conditions of water flows, and to furnish a continuous supply of timber for the use and necessities of citizens''; and

Whereas, it has long been the intent and policy of the federal government to hold rural communities harmless from the creation of federal lands and in 1906 the Committee on Public Lands recognized that the presence of federal lands could create a hardship for many counties, as they provided little revenue or commerce at that time; and

Whereas, in 1908, Congress created the Twenty-five Percent Fund Act to pay states and and counties 25 percent of receipts collected from national forests and mandated that payments were to be spent on schools and roads, recognizing that viable communities adjacent to the public lands, with adequate roads and schools, were essential for the development and preservation of the national forests; and

Whereas, the federal policy of holding counties harmless from the creation of public lands within counties was reiterated in 1916 with the creation of the Oregon and California Grant Lands under the Chamberlain-Ferris Act, and again in 1937 with passage of the Oregon and California Grant Lands Act; and

Whereas, the forest resources were intended to be managed in such an environmentally responsible manner that they would produce long-term sustainable revenue to share with schools and counties as well as products for the nation; and

Whereas, in 2000, Congress passed the Secure Rural Schools and Community Self-Determination Act, commonly known as public law 106–393, which restored historical payment levels previously made to states and counties from the federal government for road and school purposes due to declining levels of actual forest receipts; and

Whereas, the reauthorization of public law 106–393 is pending before the United States Congress and Idaho counties are on record as being strongly supportive of a fully-funded approval of this Act; and

Whereas, recently, federal land managers have been faced with an ever-present funding shortage and rural counties will be faced with higher property taxes or a reduction in services if the Secure Rural Schools and Community Self-Determination Act is not reauthorized and appropriated; and

Whereas, there is continued concern that if the Act is reauthorized and appropriated it may be the last time it occurs and a long-term solution to these issues is necessary; and

Whereas, the state of Idaho is dependent upon healthy national forest system lands for economic benefit, recreation and scenic beauty and it is time to demonstrate a new initiative and commitment to the intent and policy of the federal government to hold counties and schools harmless from the creation of federal lands and construct a path leading to economic stability for rural communities and schools; and

Whereas, transfer of the management of the national forest system lands that are not designated as wilderness, proposed or recommended wilderness, wild and scenic river, or national recreation area, or designated roadless area in Idaho, to the state of Idaho would promote better stewardship of the public lands, provide financial returns to the counties, secure public access, meet Congress's intent to hold rural communities harmless from the creation of federal lands, and fund schools, road and bridge infrastructure which would offset significant tax increases in rural counties in the event the Secure Rural Schools payments are not reauthorized or are allowed to expire following the 2006 reauthorization; and

Whereas, precedent for state administration of federally-owned lands exists in the state of Idaho at the City of Rocks area in southern Idaho and campground-related facilities and land at Lake Cascade; and

Whereas, a transfer of management to the state of Idaho would demonstrate a new initiative and commitment to the intent and policy of the federal government to hold rural counties and schools harmless from the consequences of the reservation of federal lands and construct a process leading to economic stability for rural communities and schools; and

Whereas, lands for which management responsibility is transferred to the state of Idaho could be administered by the Idaho Department of Lands in cooperation with county officials and with cooperative oversight by the United State Forest Service and state and local government could establish, or use existing natural resource advisory committees composed of a diverse cross-section of the public, with all decisions and actions relating to the lands being required to comply with every federal and state environmental law; and

Whereas, the management of these lands would have to meet the mandates of the Healthy Forest Initiative, the National Fire Plan, and state and county fire mitigation plans: Now, therefore, be it

Resolved by the members of the Second Regular Session of the Fifty-eighth Idaho Legislature, the House of Representatives and the Senate concurring therein, That we urge the Congress to support federal legislation transferring management of national forest system lands within Idaho to the state of Idaho to be managed for the benefit of the rural counties and schools with the state of Idaho being held harmless from the costs of administration; and be it further

Resolved, That Congress is urged to provide that any transfer of management authority would not affect any rights or authority of the state with respect to fish and wildlife, or repeal or modify any provision of law that permits the state or political subdivisions of the state to share in the revenues from federal lands, or any provision of law that provides that fees or charges collected at particular federal areas be used for or credited to specific purposes or special funds; and be it further

Resolved, That Congress is urged to provide that fees or revenues collected under state management be allocated 75 percent, or other appropriate percentage, for the benefit of the counties and schools in which the national forest system lands are located and 25 percent, or other appropriate percentage, for the benefit of the national forest in which the lands administered by the state of Idaho are located to be paid at the end of the year to the Secretary of the Treasury, and that amounts allocated to the counties should not be taken into account for purposes of the Twenty-five Percent Fund pursuant to 16 U.S.C. Section 500; and be it further

Resolved, That Congress is urged to seek a long-term solution to the significant issues that will face rural counties in the event the Secure Rural Schools payments are not reauthorized or are allowed to expire following the 2006 reauthorization; and be it further

Resolved, That the Chief Clerk of the House of Representatives be, and she is hereby authorized and directed to forward a copy of this Memorial to the President of the Senate and the Speaker of the House of Representatives of Congress, and the congressional delegation representing the State of Idaho in the Congress of the United States.

POM–78. A concurrent resolution adopted by the House of Representatives of the Legislature of the State of Idaho stating findings of the Legislature and authorizing the legislative council to appoint a committee to undertake and complete a study of the decline in receipts on National Forest System Lands; to the Committee on Energy and Natural Resources.

HOUSE CONCURRENT RESOLUTION NO. 26

Whereas, it has long been the intent and policy of the federal government to hold rural communities harmless from the creation of federal lands and in 1906 the Committee on Public Lands recognized that the presence of federal lands could create hardship for many counties as they provided little revenue or commerce at that time; and

Whereas, in 1908, the federal government promised rural counties 25 percent of all revenues generated from the multiple-use management of the newly created national forests to support public roads and public schools; and

Whereas, in recent decades, the forest resources have not been managed in a manner to produce long-term sustainable revenue to share with schools and counties; and

Whereas, in 2000, Congress passed Public Law 106–393, the Secure Rural Schools and Community Self-Determination Act. The Act restored historical payment levels previously made to states and counties from the federal government for road and school purposes because of declining levels of actual forest receipts; and

Whereas, the reauthorization and appropriation of the Secure Rural Schools and Community Self-Determination Act is pending before the United States Congress, and Idaho counties are on record as being strongly supportive of a fully funded approval of this Act; and

Whereas, federal land managers continue to be faced with funding shortages. In the event the Secure Rural Schools and Community Self-Determination Act is not reauthorized and appropriated, counties will be faced with higher property taxes or a reduction in services and, even if the Act is reauthorized and appropriated, it will likely be the last time, and the state of Idaho must seek a long-term solution; and

Whereas, in 2006, House Joint Memorial No. 21 was adopted by the members of the Second Regular Session of the Fifty-eighth Idaho Legislature to provide one option to address the problem of declining forest receipts by urging Congress to support federal legislation transferring management of National Forest System lands within Idaho to the state of Idaho to be managed for the benefit of the rural counties and schools: Now, therefore, be it

Resolved by the members of the First Regular Session of the Fifty-ninth Idaho Legislature, the House of Representatives and the Senate concurring therein, that the Legislative Council is authorized to appoint an interim committee to undertake and complete an assessment of the decline in receipts on National Forest System lands, which have historically been shared with counties, with the goal of the interim committee's recommendations being to develop a federal, bipartisan, long-term solution that addresses sustainable management of federal forest lands to stabilize payments to Idaho's forest counties, which help support roads and schools, and to provided projects that enhance forest ecosystem health and provide employment opportunities, and to improve cooperative relationships among those who use and care about the lands the agencies manage. The Legislative Council shall determine the membership from each house appointed to the interim committee and shall authorize the interim committee to receive input, advice and assistance from interested and affected parties who are not members of the Legislature. As much as is practicable, the interim committee shall work in cooperation and coordination with the state of Idaho, its counties, its school and highway districts, along with the recognized Indian tribes of the state of Idaho. The interim committee is also authorized to retain the services of consultants, within appropriated moneys, who are familiar with forest receipts, and who can provide necessary economic and other research to assist the interim committee and the Legislature in making an informed decision on this most important topic; and now, therefore, be it further

Resolved, That the Idaho legislative interim committee on forest receipts will address National Forest System lands, but only those lands that do not have special designations. The interim committee is directed to formulate a solution that will protect all valid existing rights, existing public access

and activities, including hunting, fishing and recreation, and that will not be construed to interfere with treaties or any other obligations to the Indian tribes, commitments to county governments, or the General Mining Law or Taylor Grazing Act; and now, therefore, be it further

Resolved, That nonlegislative members of the interim committee may be appointed by the cochairs of the interim committee who are appointed by the Legislative Council. Nonlegislative members of the interim committee shall not be reimbursed from legislative funds for per diem, mileage or other expenses and shall not have voting privileges regarding the interim committee's recommendations or proposed legislation; and now, therefore, be it further

Resolved, That the interim committee shall report its findings, recommendations and proposed legislation, if any, to the Second Regular Session of the Fifty-ninth Idaho Legislature.

EXECUTIVE REPORT OF COMMITTEE

The following executive report of a nomination was submitted:

By Mr. BINGAMAN for the Committee on Energy and Natural Resources.

*Steven Jeffrey Isakowitz, of Virginia, to be Chief Financial Officer, Department of Energy.

*Nomination was reported with recommendation that it be confirmed subject to the nominee's commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. ENZI (for himself, Mr. ALEXANDER, Mr. ALLARD, Mr. BURR, Mr. ISAKSON, Ms. MURKOWSKI, and Mr. ROBERTS):

S. 1262. A bill to protect students receiving student loans, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

By Ms. CANTWELL (for herself, Mr. SMITH, Mr. KERRY, Mrs. BOXER, Mr. NELSON of Florida, Mrs. MCCASKILL, Mr. ROCKEFELLER, Mrs. MURRAY, Mrs. FEINSTEIN, Mr. BIDEN, Ms. STABENOW, Mr. WYDEN, Mr. REED, Mr. DORGAN, Mr. DURBIN, and Mr. HARKIN):

S. 1263. A bill to protect the welfare of consumers by prohibiting price gouging with respect to gasoline and petroleum distillates during natural disasters and abnormal market disruptions, and for other purposes; to the Committee on Commerce, Science, and Transportation.

By Mr. COLEMAN (for himself and Mr. PRYOR):

S. 1264. A bill to amend the Internal Revenue Code of 1986 to provide a credit to holders of rural renaissance bonds; to the Committee on Finance.

By Mr. CRAIG:

S. 1265. A bill to amend title 38, United States Code, to expand eligibility for veterans' mortgage life insurance to include members of the Armed Forces receiving specially adapted housing assistance from the Department of Veterans Affairs; to the Committee on Veterans' Affairs.

By Mr. CRAIG:

S. 1266. A bill to amend title 38, United States Code, to increase assistance for veterans interred in cemeteries other than national cemeteries, and for other purposes; to the Committee on Veterans' Affairs.

By Mr. LUGAR (for himself, Mr. DODD, Mr. GRAHAM, Mr. DOMENICI, and Ms. LANDRIEU):

S. 1267. A bill to maintain the free flow of information to the public by providing conditions for the federally compelled disclosure of information by certain persons connected with the news media; to the Committee on the Judiciary.

By Mr. DORGAN (for himself and Mr. CRAIG):

S. 1268. A bill to provide for the development and inventory of certain outer Continental Shelf resources; to the Committee on Energy and Natural Resources.

By Mr. INHOFE:

S. 1269. A bill to improve border security in the United States and for other purposes; to the Committee on the Judiciary.

By Mr. AKAKA (for himself, Mr. KENNEDY, Mr. INOUYE, Mr. OBAMA, Mr. DURBIN, Mr. HARKIN, Mr. SALAZAR, and Mr. ISAKSON):

S. 1270. A bill to amend title IV of the Employee Retirement Income Security Act of 1974 to require the Pension Benefit Guaranty Corporation, in the case of airline pilots who are required by regulation to retire at age 60, to compute the actuarial value of monthly benefits in the form of a life annuity commencing at age 60; to the Committee on Health, Education, Labor, and Pensions.

By Mr. OBAMA (for himself and Mrs. MCCASKILL):

S. 1271. A bill to provide for a comprehensive national research effort on the physical and mental health and other readjustment needs of the members of the Armed Forces and veterans who served in Operation Iraqi Freedom and Operation Enduring Freedom and their families; to the Committee on Armed Services.

By Mr. CHAMBLISS (for himself, Mr. COLEMAN, Ms. KLOBUCHAR, and Mr. ISAKSON):

S. 1272. A bill to establish the National Guard Yellow Ribbon Reintegration Program; to the Committee on Armed Services.

By Mr. KYL:

S. 1273. A bill to amend the Internal Revenue Code of 1986 to allow permanent lookthrough treatment of payments between related foreign corporations; to the Committee on Finance.

By Mr. DURBIN:

S. 1274. A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food for humans and pets; to the Committee on Health, Education, Labor, and Pensions.

By Mr. SCHUMER (for himself and Mrs. CLINTON):

S. 1275. A bill to amend the Public Health Service Act and title XIX of the Social Security Act to provide for a screening and treatment program for prostate cancer in the same manner as is provided for breast and cervical cancer; to the Committee on Finance.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. DODD:

S. Con. Res. 30. A concurrent resolution urging all sides to the current political crisis in Ukraine to act responsibly and use dialogue to resolve the crisis and ensure a free and transparent democratic system in Ukraine based on the rule of law; to the Committee on Foreign Relations.

ADDITIONAL COSPONSORS

S. 57

At the request of Mr. INOUYE, the name of the Senator from Alaska (Mr. STEVENS) was added as a cosponsor of S. 57, a bill to amend title 38, United States Code, to deem certain service in the organized military forces of the Government of the Commonwealth of the Philippines and the Philippine Scouts to have been active service for purposes of benefits under programs administered by the Secretary of Veterans Affairs.

S. 154

At the request of Mr. BUNNING, the name of the Senator from West Virginia (Mr. BYRD) was added as a cosponsor of S. 154, a bill to promote coal-to-liquid fuel activities.

S. 155

At the request of Mr. BUNNING, the name of the Senator from West Virginia (Mr. BYRD) was added as a cosponsor of S. 155, a bill to promote coal-to-liquid fuel activities.

S. 291

At the request of Mr. SMITH, the name of the Senator from Minnesota (Ms. KLOBUCHAR) was added as a cosponsor of S. 291, a bill to establish a digital and wireless network technology program, and for other purposes.

S. 311

At the request of Ms. LANDRIEU, the names of the Senator from Hawaii (Mr. INOUYE) and the Senator from West Virginia (Mr. ROCKEFELLER) were added as cosponsors of S. 311, a bill to amend the Horse Protection Act to prohibit the shipping, transporting, moving, delivering, receiving, possessing, purchasing, selling, or donation of horses and other equines to be slaughtered for human consumption, and for other purposes.

S. 329

At the request of Mrs. LINCOLN, the names of the Senator from Ohio (Mr. BROWN) and the Senator from South Dakota (Mr. JOHNSON) were added as cosponsors of S. 329, a bill to amend title XVIII of the Social Security Act to provide coverage for cardiac rehabilitation and pulmonary rehabilitation services.

S. 334

At the request of Mr. WYDEN, the name of the Senator from Utah (Mr. BENNETT) was added as a cosponsor of S. 334, a bill to provide affordable, guaranteed private health coverage that will make Americans healthier and can never be taken away.

S. 367

At the request of Mr. DORGAN, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 367, a bill to amend the Tariff Act of 1930 to prohibit the import, export, and sale of goods made with

sweatshop labor, and for other purposes.

S. 392

At the request of Mr. BIDEN, the name of the Senator from Illinois (Mr. DURBIN) was added as a cosponsor of S. 392, a bill to ensure payment of United States assessments for United Nations peacekeeping operations for the 2005 through 2008 time period.

S. 430

At the request of Mr. LEAHY, the name of the Senator from North Dakota (Mr. DORGAN) was added as a cosponsor of S. 430, a bill to amend title 10, United States Code, to enhance the national defense through empowerment of the Chief of the National Guard Bureau and the enhancement of the functions of the National Guard Bureau, and for other purposes.

S. 442

At the request of Mr. DURBIN, the names of the Senator from New Jersey (Mr. LAUTENBERG), the Senator from Colorado (Mr. SALAZAR), the Senator from Hawaii (Mr. AKAKA), the Senator from Ohio (Mr. BROWN), the Senator from New Jersey (Mr. MENENDEZ), the Senator from California (Mrs. BOXER), the Senator from Washington (Mrs. MURRAY), the Senator from Connecticut (Mr. LIEBERMAN), the Senator from Michigan (Mr. LEVIN), the Senator from Arkansas (Mr. PRYOR) and the Senator from Vermont (Mr. SANDERS) were added as cosponsors of S. 442, a bill to provide for loan repayment for prosecutors and public defenders.

S. 450

At the request of Mrs. LINCOLN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 450, a bill to amend title XVIII of the Social Security Act to repeal the medicare outpatient rehabilitation therapy caps.

S. 458

At the request of Mrs. LINCOLN, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 458, a bill to amend title XVIII of the Social Security Act to provide for the treatment of certain physician pathology services under the Medicare program.

S. 506

At the request of Mr. LAUTENBERG, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 506, a bill to improve efficiency in the Federal Government through the use of high-performance green buildings, and for other purposes.

S. 545

At the request of Mr. LOTT, the name of the Senator from New Hampshire (Mr. SUNUNU) was added as a cosponsor of S. 545, a bill to improve consumer access to passenger vehicle loss data held by insurers.

S. 557

At the request of Mr. SCHUMER, the name of the Senator from North Carolina (Mr. BURR) was added as a cosponsor of S. 557, a bill to amend the Internal Revenue Code of 1986 to make permanent the depreciation classification of motorsports entertainment complexes.

S. 558

At the request of Mr. DOMENICI, the name of the Senator from Virginia (Mr. WEBB) was added as a cosponsor of S. 558, a bill to provide parity between health insurance coverage of mental health benefits and benefits for medical and surgical services.

S. 591

At the request of Mr. CHAMBLISS, the names of the Senator from Indiana (Mr. LUGAR) and the Senator from Illinois (Mr. DURBIN) were added as cosponsors of S. 591, a bill to amend the Food Stamp Act of 1977 to adjust for inflation the allowable amounts of financial resources of eligible households and to exclude from countable financial resources certain retirement and education accounts.

S. 594

At the request of Mrs. FEINSTEIN, the name of the Senator from Wisconsin (Mr. FEINGOLD) was added as a cosponsor of S. 594, a bill to limit the use, sale, and transfer of cluster munitions.

S. 597

At the request of Mrs. FEINSTEIN, the names of the Senator from Kansas (Mr. ROBERTS) and the Senator from Indiana (Mr. LUGAR) were added as cosponsors of S. 597, a bill to extend the special postage stamp for breast cancer research for 2 years.

S. 609

At the request of Mr. ROCKEFELLER, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 609, a bill to amend section 254 of the Communications Act of 1934 to provide that funds received as universal service contributions and the universal service support programs established pursuant to that section are not subject to certain provisions of title 31, United States Code, commonly known as the Antideficiency Act.

S. 617

At the request of Mr. SMITH, the names of the Senator from Idaho (Mr. CRAIG) and the Senator from New Mexico (Mr. DOMENICI) were added as cosponsors of S. 617, a bill to make the National Parks and Federal Recreational Lands Pass available at a discount to certain veterans.

S. 638

At the request of Mr. ROBERTS, the names of the Senator from North Carolina (Mrs. DOLE), the Senator from Louisiana (Ms. LANDRIEU) and the Senator from Virginia (Mr. WARNER) were added as cosponsors of S. 638, a bill to amend the Internal Revenue Code of 1986 to provide for collegiate housing and infrastructure grants.

S. 673

At the request of Mr. SALAZAR, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of S. 673, a bill to amend the Internal Revenue Code of 1986 to provide credits for the installation of wind energy property, including by rural homeowners, farmers, ranchers, and small businesses, and for other purposes.

S. 721

At the request of Mr. ENZI, the name of the Senator from Virginia (Mr. WEBB) was added as a cosponsor of S. 721, a bill to allow travel between the United States and Cuba.

S. 773

At the request of Mr. WARNER, the name of the Senator from Washington (Mrs. MURRAY) was added as a cosponsor of S. 773, a bill to amend the Internal Revenue Code of 1986 to allow Federal civilian and military retirees to pay health insurance premiums on a pretax basis and to allow a deduction for TRICARE supplemental premiums.

S. 838

At the request of Mr. SMITH, the name of the Senator from New Jersey (Mr. MENENDEZ) was added as a cosponsor of S. 838, a bill to authorize funding for eligible joint ventures between United States and Israeli businesses and academic persons, to establish the International Energy Advisory Board, and for other purposes.

S. 881

At the request of Mrs. LINCOLN, the names of the Senator from Mississippi (Mr. COCHRAN) and the Senator from Alaska (Ms. MURKOWSKI) were added as cosponsors of S. 881, a bill to amend the Internal Revenue Code of 1986 to extend and modify the railroad track maintenance credit.

S. 901

At the request of Mr. KENNEDY, the name of the Senator from New Jersey (Mr. LAUTENBERG) was added as a cosponsor of S. 901, a bill to amend the Public Health Service Act to provide additional authorizations of appropriations for the health centers program under section 330 of such Act.

S. 902

At the request of Mr. HARKIN, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 902, a bill to provide support and assistance for families of members of the National Guard and Reserve who are undergoing deployment, and for other purposes.

S. 937

At the request of Mrs. CLINTON, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 937, a bill to improve support and services for individuals with autism and their families.

S. 946

At the request of Mr. DURBIN, the name of the Senator from Washington (Ms. CANTWELL) was added as a cosponsor of S. 946, a bill to amend the Farm Security and Rural Investment Act of 2002 to reauthorize the McGovern-Dole International Food for Education and Child Nutrition Program, and for other purposes.

S. 961

At the request of Mr. NELSON of Nebraska, the names of the Senator from

Washington (Ms. CANTWELL), the Senator from Colorado (Mr. SALAZAR), the Senator from Vermont (Mr. SANDERS), the Senator from Michigan (Ms. STABENOW), the Senator from South Dakota (Mr. JOHNSON) and the Senator from Missouri (Mr. BOND) were added as cosponsors of S. 961, a bill to amend title 46, United States Code, to provide benefits to certain individuals who served in the United States merchant marine (including the Army Transport Service and the Naval Transport Service) during World War II, and for other purposes.

S. 972

At the request of Mr. LAUTENBERG, the name of the Senator from Vermont (Mr. SANDERS) was added as a cosponsor of S. 972, a bill to provide for the reduction of adolescent pregnancy, HIV rates, and other sexually transmitted diseases, and for other purposes.

S. 1003

At the request of Ms. STABENOW, the name of the Senator from Michigan (Mr. LEVIN) was added as a cosponsor of S. 1003, a bill to amend title XVIII of the Social Security Act to improve access to emergency medical services and the quality and efficiency of care furnished in emergency departments of hospitals and critical access hospitals by establishing a bipartisan commission to examine factors that affect the effective delivery of such services, by providing for additional payments for certain physician services furnished in such emergency departments, and by establishing a Centers for Medicare & Medicaid Services Working Group, and for other purposes.

S. 1038

At the request of Mr. CORNYN, the name of the Senator from New Mexico (Mr. DOMENICI) was withdrawn as a cosponsor of S. 1038, a bill to amend the Internal Revenue Code of 1986 to expand workplace health incentives by equalizing the tax consequences of employee athletic facility use.

S. 1083

At the request of Mr. CORNYN, the name of the Senator from New Mexico (Mr. DOMENICI) was added as a cosponsor of S. 1083, a bill to amend the Immigration and Nationality Act to increase competitiveness in the United States, and for other purposes.

S. 1129

At the request of Mr. SMITH, the name of the Senator from South Dakota (Mr. JOHNSON) was added as a cosponsor of S. 1129, a bill to amend the Internal Revenue Code of 1986 to modify the definition of governmental plan with respect to Indian tribal governments.

S. 1164

At the request of Mr. CARDIN, the name of the Senator from North Dakota (Mr. CONRAD) was added as a cosponsor of S. 1164, a bill to amend title XVIII of the Social Security Act to improve patient access to, and utilization of, the colorectal cancer screening benefit under the Medicare Program.

S. 1173

At the request of Mrs. BOXER, the name of the Senator from Ohio (Mr. BROWN) was added as a cosponsor of S. 1173, a bill to protect, consistent with Roe v. Wade, a woman's freedom to choose to bear a child or terminate a pregnancy, and for other purposes.

S. 1185

At the request of Mr. BINGAMAN, the name of the Senator from Nevada (Mr. REID) was added as a cosponsor of S. 1185, a bill to provide grants to States to improve high schools and raise graduation rates while ensuring rigorous standards, to develop and implement effective school models for struggling students and dropouts, and to improve State policies to raise graduation rates, and for other purposes.

S. 1190

At the request of Mr. DURBIN, the names of the Senator from Maine (Ms. SNOWE), the Senator from Tennessee (Mr. ALEXANDER), the Senator from New Mexico (Mr. BINGAMAN) and the Senator from Louisiana (Ms. LANDRIEU) were added as cosponsors of S. 1190, a bill to promote the deployment and adoption of telecommunications services and information technologies, and for other purposes.

S. 1205

At the request of Mr. SMITH, the name of the Senator from Massachusetts (Mr. KENNEDY) was added as a cosponsor of S. 1205, a bill to require a pilot program on assisting veterans service organizations and other veterans groups in developing and promoting peer support programs that facilitate community reintegration of veterans returning from active duty, and for other purposes.

S. 1237

At the request of Mr. LAUTENBERG, the name of the Senator from Maryland (Ms. MIKULSKI) was added as a cosponsor of S. 1237, a bill to increase public safety by permitting the Attorney General to deny the transfer of firearms or the issuance of firearms and explosives licenses to known or suspected dangerous terrorists.

S. 1257

At the request of Mr. LIEBERMAN, the names of the Senator from New York (Mrs. CLINTON), the Senator from Louisiana (Ms. LANDRIEU) and the Senator from Vermont (Mr. LEAHY) were added as cosponsors of S. 1257, a bill to provide the District of Columbia a voting seat and the State of Utah an additional seat in the House of Representatives.

S. CON. RES. 26

At the request of Mrs. CLINTON, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. Con. Res. 26, a concurrent resolution recognizing the 75th anniversary of the Military Order of the Purple Heart and commending recipients of the Purple Heart for their courageous demonstrations of gallantry and heroism on behalf of the United States.

S. CON. RES. 27

At the request of Mrs. CLINTON, the name of the Senator from Mississippi (Mr. COCHRAN) was added as a cosponsor of S. Con. Res. 27, a concurrent resolution supporting the goals and ideals of ''National Purple Heart Recognition Day''.

S. RES. 183

At the request of Ms. LANDRIEU, the names of the Senator from Colorado (Mr. ALLARD) and the Senator from Georgia (Mr. CHAMBLISS) were added as cosponsors of S. Res. 183, a resolution supporting the goals and ideals of National Charter Schools Week, April 30, 2007, through May 4, 2007.

AMENDMENT NO. 982

At the request of Mr. ALLARD, the names of the Senator from Missouri (Mr. BOND), the Senator from Utah (Mr. HATCH) and the Senator from Tennessee (Mr. ALEXANDER) were added as cosponsors of amendment No. 982 proposed to S. 1082, a bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

AMENDMENT NO. 993

At the request of Mr. GREGG, the name of the Senator from Minnesota (Mr. COLEMAN) was added as a cosponsor of amendment No. 993 proposed to S. 1082, a bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

AMENDMENT NO. 1004

At the request of Ms. LANDRIEU, the name of the Senator from Louisiana (Mr. VITTER) was added as a cosponsor of amendment No. 1004 proposed to S. 1082, a bill to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. ENZI (for himself, Mr. ALEXANDER, Mr. ALLARD, Mr. BURR, Mr. ISAKSON, Ms. MURKOWSKI, and Mr. ROBERTS):

S. 1262. A bill to protect students receiving student loans, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

S. 1262

Mr. ENZI. Mr. President, I rise to speak about the Student Loan Accountability and Disclosure Reform Act which I, along with Senators ALEXANDER, BURR, ISAKSON, ALLARD and MURKOWSKI, am introducing today. In this era of rising college costs, it is more important than ever to make sure that the colleges, lenders and guaranty agencies that provide loans to help students pay for college operate in a fair, accountable and transparent manner.

In fiscal year 2007, the Federal Government, through the Federal Family Education Loan, FFEL, and Direct

Loan programs is expected to back and provide $65.9 billion in new loans to students and their parents for attendance at over 6,000 schools. The FFEL program accounts for about 79 percent of new student loan volume. There are approximately 3,200 FFEL lenders. Thirty-five State and private, nonprofit guaranty agencies back the FFEL loans.

Overall, the programs are expected to provide financing to 14.3 million students and their families this year. These students and their families are depending upon us to protect them from those individuals who are using the financial loan programs to benefit themselves to the detriment of students.

The focus of this bill is to make colleges, lenders and guaranty agencies accountable, by prohibiting lenders and guaranty agencies from offering inducements, and colleges from accepting them, and by requiring disclosures to students, their families and the public.

There are a lot of ethical, hard-working financial aid administrators and lenders who have spent their lives helping students go to college. It is a shame that a few bad actors have cast a shadow over the whole student loan industry. However, in light of recent revelations about the behavior of a few college officials and a few lenders, it is clear that we need to take steps to protect students and their families from any actions and arrangements that are not fully disclosed.

A key part of this bill is a Code of Conduct for institutions of higher education. It prohibits colleges and their employees with responsibility for student financial aid from receiving anything of value from any lender in exchange for advantages sought by the lender. The prohibition applies not only to gifts and trips, but to compensation for service on advisory boards and consulting contracts.

Colleges are prohibited from designating ''preferred lenders.'' However, they may collect information from lenders, at the college's invitation or upon the request of a lender, including interest rates, payment of origination and other fees, discounts, services and terms and conditions of the loans, and the lender's contact information, on a standard electronic template. All templates submitted will be made available to current and prospective students and their families. Colleges will provide students and parents with a guide that enables the students and parents to do their own evaluation of the loan products, benefits, and services offered by the lenders. An annual attestation of college compliance by a high level college official with the Code of Conduct is required.

The bill expands prohibitions on guaranty agencies and lenders, including provisions that prohibit the offering of any premiums, payments, prizes, and tuition payments. Guaranty agencies are precluded from performing any services for colleges without compensation. Lenders may not provide information technology equipment at below market value. Both lenders and guaranty agencies are prohibited from sending unsolicited electronic mailings to potential borrowers.

Finally, the recent revelations of questionable relationships between colleges and lenders have led to new calls to eliminate any areas of potential conflicts of interest. For this reason, it is time to phase out the ability of colleges to act as lenders in the FFEL program, a provision commonly referred to as ''school-as-lender.''

Higher education is crucial to maintaining America's competitiveness. Education at all levels, including lifelong education opportunities, is vital to ensuring that America retains its competitive edge in the global economy. In this global economy, learning is never over and school is never out. If students and families are to make informed decisions about how to pay for college, they must have clear, accurate, comprehensive information on which to base their decisions.

We must help and protect the 14.3 million students and their families who will seek student loans this year to pay for the education they need. Therefore, we must maintain the integrity of the student loan programs. Let's fix the system and restore the confidence of students that they are being treated fairly from the beginning, and through the time they are repaying their loans and realizing their goals.

I want to thank Senators ALEXANDER, BURR, ISAKSON, ALLARD, and MURKOWSKI for joining me in this effort.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1262

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Student Loan Accountability and Disclosure Reform Act''.

SEC. 2. INSURANCE PROGRAM AGREEMENTS.

Paragraph (3) of section 428(b) of the Higher Education Act of 1965 (20 U.S.C. 1078(b)(3)) is amended to read as follows:

''(3) RESTRICTIONS ON INDUCEMENTS, PAYMENTS, MAILINGS, AND ADVERTISING.—A guaranty agency shall not—

''(A) offer, directly or indirectly, premiums, payments, stock or other securities, prizes, travel, entertainment expenses, tuition repayment, or other inducements to—

''(i) any institution of higher education or the employees of an institution of higher education in order to secure applicants for loans made under this part; or

''(ii) any lender, or any agent, employee, or independent contractor of any lender or guaranty agency, in order to administer or market loans made under this part (other than a loan made under section 428H or a loan made as part of the guaranty agency's lender-of-last-resort program pursuant to section 439(q)) for the purpose of securing the designation of the guaranty agency as the insurer of such loans;

''(B) conduct unsolicited mailings, by postal or electronic means, of student loan application forms to students enrolled in secondary school or postsecondary educational institutions, or to the parents of such students, except that applications may be mailed, by postal or electronic means, to students or borrowers who have previously received loans guaranteed under this part by the guaranty agency;

''(C) perform, for an institution of higher education participating in a program under this title and without appropriate compensation by such institution, any function that the institution is required to perform under part B, D, or G (except for the exit counseling described in section 485(b));

''(D) pay, on behalf of the institution of higher education, another person to perform any function that the institution of higher education is required to perform under part B, D, or G (except for the exit counseling described in section 485(b)); or

''(E) conduct fraudulent or misleading advertising concerning loan availability, terms, or conditions.

It shall not be a violation of this paragraph for a guaranty agency to provide assistance to institutions of higher education comparable to the kinds of assistance provided to institutions of higher education by the Department.''.

SEC. 3. DISCLOSURE RULES FOR EDUCATIONAL LOANS.

Title I of the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.) is amended by adding at the end the following:

''PART E—DISCLOSURE RULES FOR EDUCATIONAL LOANS

''SEC. 151. DISCLOSURE RULES RELATING TO EDUCATIONAL LOANS.

''(a) DEFINITIONS.—In this part:

''(1) COST OF ATTENDANCE.—The term 'cost of attendance' has the meaning given the term in section 472.

''(2) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education'—

''(A) has the meaning given the term in section 102; and

''(B) includes an employee or agent of the institution of higher education or any organization or entity directly or indirectly controlled by such institution.

''(3) LENDER.—The term 'lender' means—

''(A) any lender of a loan made, insured, or guaranteed under title IV, including a consolidation loan under section 428C;

''(B) any lender that is a financial institution, as such term is defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809); and

''(C) for any loan issued or provided to a student under part D of title IV, the Secretary.

''(4) PRIVATE EDUCATIONAL LOAN.—The term 'private educational loan' means a private loan that—

''(A) is not made, insured, or guaranteed under title IV; and

''(B) is offered to a borrower by an institution of higher education through an award letter or other notification.

''(b) DISCLOSURES.—

''(1) DISCLOSURES BY LENDERS.—Before a lender issues or otherwise provides a loan under title IV or a private educational loan to a student, the lender shall provide the student, in writing, with the disclosures described in paragraph (2).

''(2) DISCLOSURES.—The disclosures required by this paragraph shall include a clear and prominent statement—

''(A) that the borrower may qualify for Federal financial assistance through a program under title IV, in lieu of or in addition to a loan from a non-Federal source;

''(B) of the interest rates available with respect to such Federal financial assistance;

''(C) showing sample educational loan costs, disaggregated by type;

''(D) that describes, with respect to each loan being provided to the student by the lender—

''(i) how the applicable interest rate is determined, including whether the rate is based on the credit score of the borrower;

''(ii) the types of repayment plans that are available;

''(iii) whether, and under what conditions, early repayment may be made without penalty;

''(iv) when and how often the loan would be recapitalized;

''(v) all fees, deferments, or forbearance;

''(vi) all available repayment benefits, and the percentage of all borrowers who qualify for such benefits;

''(vii) the collection practices in the case of default;

''(viii) the late payment penalties and associated fees; and

''(ix) whether the amount of all loans issued by the lender to the borrower exceeds the student's cost of attendance; and

''(E) such other information as the Secretary may require.''.

SEC. 4. REVIEW OF PRIVATE EDUCATIONAL LOAN MARKET.

Section 495 of the Higher Education Act of 1965 (20 U.S.C. 1099a) is amended by adding at the end the following:

''(c) REVIEW OF PRIVATE EDUCATION LOAN MARKETS.—The Secretary and the Secretary of the Treasury shall conduct an evaluation of markets for educational loans to—

''(1) evaluate any variations in availability, terms, and conditions of educational loans provided to students who qualify for a simplified needs test under section 479 or any income-contingent simplified version of the Free Application for Federal Student Aid;

''(2) identify possible discriminatory lending patterns affecting students described in paragraph (1); and

''(3) report, not later than 1 year after the date of enactment of the Student Loan Accountability and Disclosure Reform Act to the Committee on Health, Education, Labor, and Pensions and the Committee on Banking, Housing, and Urban Affairs of the Senate, and the Committee on Education and Labor and the Committee on Financial Services of the House of Representatives, on findings and recommendations for the need to afford protections from predatory lending practices to such students.''.

SEC. 5. DISQUALIFICATION OF ELIGIBLE LENDER.

Section 435(d)(5) of the Higher Education Act of 1965 (20 U.S.C. 1085(d)(5)) is amended—

(1) by redesignating subparagraphs (C) and (D) as subparagraphs (H) and (I), respectively; and

(2) by striking subparagraphs (A) and (B) and inserting the following:

''(A) offered, directly or indirectly, points, premiums, payments (including payments for referrals and for processing or finder fees), prizes, stock or other securities, travel, entertainment expenses, tuition repayment, the provision of information technology equipment at below-market value, additional financial aid funds, or other inducements to any institution of higher education or any employee of an institution of higher education in order to secure applicants for loans under this part;

''(B) conducted unsolicited mailings, by postal or electronic means, of student loan application forms to students enrolled in secondary school or postsecondary institutions, or to parents of such students, except that applications may be mailed, by postal or electronic means, to students or borrowers who have previously received loans under this part from such lender;

''(C) entered into any type of consulting arrangement, or other contract to provide services to a lender, with an employee who is employed in the financial aid office of an institution of higher education, or who otherwise has responsibilities with respect to student loans or other financial aid of the institution;

''(D) compensated an employee who is employed in the financial aid office of an institution of higher education, or who otherwise has responsibilities with respect to student loans or other financial aid of the institution, and who is serving on an advisory board, commission, or group established by a lender or group of lenders for providing such service, except that the eligible lender may reimburse such employee for reasonable expenses incurred in providing such service;

''(E) performed for an institution of higher education, without compensation from the institution, any function that the institution of higher education is required to carry out under part B, D, or G (except for general debt counseling, such as the exit counseling described in section 485(b));

''(F) paid, on behalf of an institution of higher education, another person to perform any function that the institution of higher education is required to perform under part B, D, or G (except for general debt counseling, such as the exit counseling described in section 485(b));

''(G) provided payments or other benefits to a student at an institution of higher education to act as the lender's representative to secure applications under this title from individual prospective borrowers, unless such student—

''(i) is also employed by the lender for other purposes; and

''(ii) made all appropriate disclosures regarding such employment;''.

SEC. 6. CERTIFICATIONS; CODE OF CONDUCT REGARDING STUDENT LOANS.

Section 487 of the Higher Education Act of 1965 (20 U.S.C. 1094) is amended—

(1) in subsection (a)—

(A) by striking paragraph (6) and inserting the following:

''(6) The institution will not provide any student with any statement or certification to a lender that qualifies the student for a loan or loans in excess of the amount that student is eligible to borrow in accordance with sections 425(a), 428(a)(2), and subparagraphs (A) and (B) of section 428(b)(1) unless—

''(A) the loan in question is a private educational loan as defined under section 151(a); and

''(B) the student does not qualify for the simplified needs test under section 479 or any income-contingent simplified version of the Free Application for Federal Student Aid.'';

(B) by redesignating paragraphs (21), (22), and (23) as (22), (23), and (24), respectively; and

(C) by inserting after paragraph (20) the following:

''(21)(A) The institution will establish, follow, and enforce a code of conduct regarding student loans that includes not less than the following:

''(i) REVENUE SHARING PROHIBITION.—The institution is prohibited from receiving anything of value from any lender in exchange for any advantage sought by the lender.

''(ii) GIFT AND TRIP PROHIBITION.—Any employee who is employed in the financial aid office of the institution, or who otherwise has responsibilities with respect to student loans or other financial aid of the institution, is prohibited from taking from any lender any gift or trip worth more than nominal value, except for reasonable expenses for professional development that will improve the efficiency and effectiveness of programs under this title and for domestic travel to such professional development.

''(iii) CONTRACTING ARRANGEMENTS.—Any employee who is employed in the financial aid office of the institution, or who otherwise has responsibilities with respect to student loans or other financial aid of the institution, shall be prohibited from entering into any type of consulting arrangement or other contract to provide services to a lender.

''(iv) ADVISORY BOARD COMPENSATION.—Any employee who is employed in the financial aid office of the institution, or who otherwise has responsibilities with respect to student loans or other financial aid of the institution, and who serves on an advisory board, commission, or group established by a lender or group of lenders shall be prohibited from receiving anything of value as compensation from the lender or group of lenders for serving on such advisory board, commission, or group, except that the employee may be reimbursed for reasonable expenses incurred in providing such service.

''(v) LENDER INFORMATION REQUIREMENTS.—The institution—

''(I) will not designate any lender as a preferred lender for loans under this title or private educational loans;

''(II) may invite a lender of such loans to submit to the institution a standard electronic template that specifies the rates, services, discounts, and terms and conditions of the loans, and the lender's contact information;

''(III) upon request of a lender interested in offering loans under this title or private educational loans to students at the institution, will provide the lender with the ability to submit the standard electronic template described in subclause (II) to the institution;

''(IV) will make all submitted standard electronic templates available to current and prospective students of the institution, and the parents of such students;

''(V) if such student, or a parent of such student, requests information on the lenders that have submitted standard electronic templates to the institution, will provide the student or parent with a guide that—

''(aa) enables students and parents to do their own evaluation of the loan products, benefits, and services offered by such lenders; and

''(bb) includes the disclosures required under clause (vi).

''(vi) DISCLOSURES.—An institution required to make the disclosures under this clause will—

''(I) disclose the criteria and process used to develop the guide described in clause (v)(V) regarding the products offered by each lender that submitted a standard electronic template, as described in clause (v)(II);

''(II) disclose which lenders listed in the guide have an agreement in place to sell the loans of the lender to another lender; and

''(III) provide a notice to the student that the student has the right to select a lender of the student's choosing, regardless of any information regarding the lender in the institution's guide under clause (v) or whether the lender submitted a standard electronic template to the institution.

''(vii) LENDER SERVICES TO INSTITUTIONS OF HIGHER EDUCATION.—

''(I) Any agent, employee, or independent contractor of a lender who is performing any service for the institution shall disclose the individual's relationship with the lender to

any students and parents for whom the individual provides such service.

''(II) Any agreement for the performance of a service by a lender for the institution shall comply with all applicable State and institution ethics laws and codes of ethics.

''(viii) INTERACTION WITH BORROWERS.—The institution will not—

''(I) for any first-time borrower, assign, through award packaging or other methods, the borrower's loan to a particular lender; and

''(II) refuse to certify, or, delay certification of, any loan in accordance with paragraph (6) based on the borrower's selection of a particular lender or guaranty agency.

''(B) The institution will designate an individual who shall be responsible for signing an annual attestation on behalf of the institution that the institution agrees to, and is in compliance with, the requirements of the code of conduct described in this paragraph. Such individual shall be the chief executive officer, chief operating officer, chief financial officer, or comparable official, of the institution, and shall annually submit the signed attestation to the Secretary.

''(C) The institution will make the code of conduct widely available to the institution's faculty members, students, and parents through a variety of means, including the institution's website.'';

(2) by redesignating subsections (d) and (e) as subsections (e) and (f), respectively; and

(3) by inserting after subsection (c) the following:

''(d) VIOLATION OF CODE OF CONDUCT REGARDING STUDENT LOANS.—

''(1) IN GENERAL.—Upon a finding by the Secretary, after reasonable notice and an opportunity for a hearing, that an institution of higher education that has entered into a program participation agreement with the Secretary under subsection (a) willfully contravened the institution's attestation of compliance with the provisions of subsection (a)(21), the Secretary may impose a penalty described in paragraph (2).

''(2) PENALTIES.—A violation of paragraph (1) shall result in the limitation, suspension, or termination of the eligibility of the institution for the loan programs under this title.''.

SEC. 7. TERMINATION OF SCHOOL-AS-LENDER PROGRAM.

Section 435(d) of the Higher Education Act of 1965 (20 U.S.C. 1085(d)) (as amended by section 5) is further amended—

(1) in paragraph (1)(E), by inserting ''subject to paragraph (8),'' before ''an eligible institution''; and

(2) by adding at the end the following:

''(8) SUNSET OF AUTHORITY FOR SCHOOL AS LENDER PROGRAM.—

''(A) SUNSET.—The authority provided under subsection (d)(1)(E) for an institution to serve as an eligible lender, and under paragraph (7) for an eligible lender to serve as a trustee for an institution of higher education or an organization affiliated with an institution of higher education, shall expire on June 30, 2008.

''(B) APPLICATION TO EXISTING INSTITUTIONAL LENDERS.—An institution that was an eligible lender under this subsection, or an eligible lender that served as a trustee for an institution of higher education or an organization affiliated with an institution of higher education under paragraph (7), before June 30, 2008, shall—

''(i) not issue any new loans in such a capacity under part B after June 30, 2008; and

''(ii) shall continue to carry out the institution's responsibilities for any loans issued by the institution under part B on or before June 30, 2008, except that, beginning on June 30, 2010, the eligible institution or trustee may, notwithstanding any other provision of this Act, sell or otherwise dispose of such loans if all profits from the divestiture are used for need-based grant programs at the institution.''.

By Mr. CRAIG:

S. 1265. A bill to amend title 38, United States Code, to expand eligibility for veterans' mortgage life insurance to include members of the Armed Forced receiving specially adapted housing assistance from the Department of Veterans Affairs; to the Committee on Veterans' Affairs.

Mr. CRAIG. Mr. President, I have sought recognition to comment on legislation I am introducing that will continue a positive trend in the provision of benefits to severely injured servicemembers and their families by making assistance available when it is needed most. My bill would give active duty servicemembers who utilize VA's specially adapted housing grant assistance with the ability to also purchase Veterans' Mortgage Life Insurance, or VMLI, through VA. Under current law, the receipt of specially adapted housing grants is the gateway to VMLI eligibility. And only those separated from service and legally classified as ''veterans'' are able to purchase coverage through VMLI.

Servicemembers and veterans who are blind, have lost the use of both their legs, and who have other severely disabling conditions are eligible to receive up to $50,000 in grants from VA to assist with needed housing adaptations, such as the widening of doorways, the construction of wheelchair ramps, and the installment of handrails. Notwithstanding this grant assistance, servicemembers and veterans must still pay any underlying mortgage that exists on the modified home. To ensure that survivors are not saddled with mortgage debt they cannot afford following the death of a severely disabled veteran, VA's VMLI program is available. Under VMLI, up to $90,000 of coverage, or coverage in the amount of any outstanding mortgage debt, whichever is less, is available. Veterans pay premiums at standard mortality rates and VA contributes subsidy payments so that all program expenses are met.

Until recently, grants under the specially adapted housing program could only be made to individuals who had separated from military service. In recognition of what can be an extremely lengthy recovery and separation process for those with profoundly disabling conditions, in 2004 we in Congress allowed housing grants to be made to active duty servicemembers. However, we did not extend the same access to VA's VMLI program for those still on active duty, an oversight that my legislation would remedy.

VA estimates that roughly 30 servicemembers per year will receive specially adapted housing grants, thus giving rise to VMLI eligibility should my bill be enacted. Because it is optional, VA expects only 15 servicemembers per year to purchase VMLI policies. Therefore, subsidy costs associated with my legislation are minimal, less than $500,000 over 10 years.

This Congress increasingly is recognizing that the benefits provided to our wounded servicemembers need to flow immediately, and that outmoded distinctions between ''veteran'' and ''active duty servicemember'' mean little when it comes to honoring our commitment to them. My legislation continues what I believe is an encouraging trend that looks at the career of a military man or woman as a continuum. It is a continuum that begins the day they enlist and it ends the day they die. Our Government's benefits should reflect that reality.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1265

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXPANSION OF ELIGIBILITY FOR VETERANS' MORTGAGE LIFE INSURANCE TO INCLUDE MEMBERS OF THE ARMED FORCES RECEIVING SPECIALLY ADAPTED HOUSING ASSISTANCE FROM THE DEPARTMENT OF VETERANS AFFAIRS.

Section 2106 of title 38, United States Code, is amended—

(1) by striking ''veteran'' each place it appears and inserting ''veteran or member of the Armed Forces'';

(2) in subsection (a), by striking ''veterans' election'' and inserting ''election of the veteran or member of the Armed Forces'';

(3) in subsection (f), by inserting '', members of the Armed Forces,'' after ''veterans''; and

(4) in subsection (i)—

(A) in paragraph (1), by striking ''veteran's indebtedness'' and inserting ''indebtedness of the veteran or member of the Armed Forces''; and

(B) in paragraph (2), by striking ''veteran's ownership'' and inserting ''ownership of the veteran or member of the Armed Forces''.

By Mr. CRAIG:

S. 1266. A bill to amend title 38, United States Code, to increase assistance for veterans interred in cemeteries other than national cemeteries, and for other purposes; to the Committee on Veterans' Affairs.

Mr. CRAIG. Mr. President, I have sought recognition to comment on legislation I am introducing that will improve the availability of dignified burials for those who have served our country. The Veterans' Dignified Burial Assistance Act of 2007 would make three improvements to programs designed to ensure that veterans are perpetually honored for their service. Let me start by describing the first improvement which had its genesis, I am proud to say, in my home State of Idaho.

We have in Idaho a State veterans' cemetery located in Boise. The cemetery was established with the help of VA's State Cemetery Grants Program, a program which pays for 100 percent of

the costs of establishing, expanding, and improving state cemeteries. Over one thousand veterans have been interred in the Idaho State Cemetery since it opened in 2004. I want to focus on 91 of those veterans who were interred through a program pioneered in Idaho called ''Missing in America.''

Through the Missing in America program Idaho cemetery officials, working with veterans' organizations and others, have actively sought to locate the unclaimed cremated remains of veterans throughout the State. They contacted funeral homes, county coroner offices, and any other place where those remains may have been located. Remarkably, they discovered the remains of 91 veterans. After verifying that they had eligibility, all 91 veterans were given a dignified burial.

I suspect what was found in Idaho would be found in other States. My legislation would incentivize other States to develop Missing in America programs like Idaho's by allowing revenue from VA's plot allowance benefit to go to states which seek out and inter unclaimed remains.

Under current law, State cemeteries may be reimbursed for the cost of interring eligible veterans. For each eligible veteran interred, a $300 plot allowance may be paid by VA. Revenue from the plot allowance is used to operate and maintain the appearance of State cemeteries. However, plot allowance revenue is not payable to States when veterans are interred more than 2 years after the permanent burial or cremation of the veteran's body. Thus, since each of the 91 veterans interred in Idaho had been left sitting on shelves in an urn for a great deal longer than 2 years, no plot allowance is payable. This doesn't make sense. Just as our system of benefits does not abandon or give up on veterans who are homeless or chronically ill, so too should our burial benefits system be designed not to abandon or give up on veterans whose remains are unclaimed. To that end, my legislation would waive the 2-year limit so that States could receive plot allowance revenue for interment of the unclaimed remains of veterans. The extra plot allowance revenue could be used to help states meet costs associated with running this program and other cemetery operation costs. Most importantly, my legislation would reward States for giving veterans what is long overdue: a fitting burial.

The second way my legislation helps to ensure dignified burials is by increasing VA's plot allowance benefit from $300 to $400. As I mentioned earlier, the plot allowance can be paid directly to a State cemetery for the interment of eligible veterans. But it can also be paid to the survivors of veterans who purchase burial space on their own in the private market. Under current law, veterans who die in a VA facility, who are in receipt of disability compensation, or who have low incomes and are in receipt of VA pension are eligible to receive the $300 plot allowance benefit. The plot allowance, created in 1973, is designed to ensure that veterans are not buried in a pauper's grave. When the benefit was created, it covered 13 percent of the average cost of an adult funeral. Today, it only covers approximately 5 percent of the cost. An independent assessment of VA burial benefits directed by Congress and published in 2000 recommended, as an option, increasing the plot allowance to $670, which at the time of the assessment represented 13 percent of the average cost of an adult funeral. Since that assessment was published, the major veterans' organizations have persistently recommended that Congress increase this benefit. In its most recent budget submission, the authors of the Independent Budget recommended that the plot allowance be increased to $745. In 2001, Congress took a first step, raising the benefit from $150 to $300. My legislation would take yet another, measured step.

Finally, my legislation would authorize $5 million per year under VA's State Cemetery Grant Program for VA to assist States in meeting operational and maintenance expenses. As I mentioned, the State Cemetery Grant Program finances the cost of establishing, expanding, or improving State cemeteries. States must agree to provide suitable land for a cemetery and they must meet administrative, operational, and maintenance costs.

My purpose in introducing this aspect of the legislation is twofold. First, VA is in the midst of the largest national cemetery expansion since the Civil War. Guiding its cemetery expansion effort was a prospective look at where and how many veterans will be living 20 years from now. Based on that prospective analysis, national cemeteries are being built in those areas of the country that have veterans' populations of 170,000 or more and that are not residing within, or expected to reside within, 75 miles of an open State or national cemetery. It is therefore highly likely that after this expansion has concluded, no additional national cemeteries will be built for quite some time. Thus, in order to serve veterans' populations in less densely populated areas in the future, VA and the States will need to rely more on the State Cemetery Grant Program. Allowing reimbursement for some maintenance or operational expenses will serve to make the program more attractive to States, which may otherwise decline to participate in the program due to budget constraints. In fact, the 2000 independent assessment I spoke about earlier made the same point, recommending Congressional consideration of amending the grant program to allow for reimbursement of the sort contemplated in my legislation.

My second purpose behind this provision is a bit more parochial. There are eight States in the country without any national cemetery, including Idaho. These are States with small or scattered veterans' populations. VA's criteria for establishing national cemeteries makes it unlikely that veterans in these States will ever have access to a national cemetery within the borders of their home State. Yet their service was national in character, and the desire for recognition of that national service through interment in a national cemetery is real, if not practical. It is my opinion that the Federal obligation to veterans residing in States like my own is therefore heightened. And if the only way to heighten that obligation is by requiring reimbursement of a greater share of the expenses now borne by the States, so be it. To my mind, this would be an equitable outcome, and one that I hope VA factors into criteria it will develop should my legislation be enacted.

Let me make one final and very important point. The cost of my legislation is in the $8 million per year range. Although I am convinced of the merits of the legislation, I am also committed to adhering to our budget rules which require that appropriate spending offsets be identified before new spending is advanced. I assure my colleagues that should my legislation be reported from the Veterans' Affairs Committee, it will be fully offset in accordance with our rules and my own principle of fiscal discipline.

In summary, the Veterans' Dignified Burial Assistance Act of 2007 will help us along in our collective goal of providing veterans with lasting resting places to honor their lives and service. This is good legislation, and I urge the support of my colleagues.

I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1266

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Veterans' Dignified Burial Assistance Act of 2007''.

SEC. 2. INCREASE IN ASSISTANCE FOR VETERANS INTERRED IN CEMETERIES OTHER THAN NATIONAL CEMETERIES.

(a) INCREASE IN PLOT OR INTERMENT ALLOWANCE.—Section 2303(b) of title 38, United States Code, is amended by striking ''$300'' each place it appears and inserting ''$400''.

(b) REPEAL OF TIME LIMITATION FOR STATE FILING FOR REIMBURSEMENT FOR INTERMENT COSTS.—

(1) IN GENERAL.—The second sentence of section 3.1604(d)(2) of title 38, Code of Federal Regulations, shall have no further force or effect as it pertains to unclaimed remains of a deceased veteran.

(2) RETROACTIVE APPLICATION.—The provision of paragraph (1) shall take effect as of October 1, 2006.

(c) GRANTS FOR OPERATION AND MAINTENANCE OF STATE VETERANS' CEMETERIES.—

(1) IN GENERAL.—Subsection (a) of section 2408 of such title is amended—

(A) by inserting ''(1)'' before ''Subject to'';

(B) by designating the second sentence as paragraph (2) and indenting the margin of such paragraph, as so designated, two ems from the left margin; and

(C) in paragraph (1), as designated by subparagraph (A) of this paragraph, by striking ''assist such State in establishing, expanding, or improving veterans' cemeteries owned by such State.'' and inserting ''assist such State in the following:

''(A) Establishing, expanding, or improving veterans' cemeteries owned by such State.

''(B) Operating and maintaining such cemeteries.''.

(2) LIMITATION ON AMOUNTS AWARDED.—Subsection (e) of such section is amended—

(A) by inserting ''(1)'' before ''Amounts''; and

(B) by adding at the end the following new paragraph:

''(2) In any fiscal year, the aggregate amount of grants awarded under this section for the purposes specified in subsection (a)(1)(B) may not exceed $5,000,000.''.

(3) CONFORMING AMENDMENTS.—(A) Subsection (b) of such section is amended—

(i) by striking ''Grants under this section'' and inserting ''Grants under this section for the purposes described in subsection (a)(1)(A)''; and

(ii) by striking ''a grant under this section'' each place it appears and inserting ''such a grant''.

(B) Subsection (d) of such section is amended by inserting '', or in operating and maintaining a veterans' cemetery,'' after ''veterans' cemetery''.

(C) Subsection (f)(1) of such section is amended by inserting '', or in operating and maintaining veterans' cemeteries,'' after ''veterans' cemeteries''.

(4) REGULATIONS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Veterans Affairs shall prescribe regulations to carry out the amendments made by this subsection.

By Mr. LUGAR (for himself, Mr. DODD, Mr. GRAHAM, Mr. DOMENICI, and Ms. LANDRIEU):

S. 1267. A bill to maintain the free flow of information to the public by providing conditions for the federally compelled disclosure of information by certain persons connected with the news media; to the Committee on the Judiciary.

Mr. LUGAR. Mr. President, I am pleased to rise today with my colleagues Senators DODD, GRAHAM, DOMENICI, and LANDRIEU to introduce the Free Flow of Information Act.

The free flow of information is an essential element of democracy. A free press promotes an open marketplace of information and provides public and private sector accountability to our Nation's electorate. By ensuring the free flow of information, citizens can work to bring about improvements in our governance and in our civic life. It is in our nation's best interest to have an independent press that is free to question, challenge, and investigate issues and stories, without concern for political party, position or who holds power. The role of the media as a conduit between government and the citizens it serves must not be devalued.

This principle that we practice at home is also one that we promote abroad. Spreading democracy abroad has become a pillar of United States foreign policy, and we have recognized that a free and independent press is both essential to building democracies and a barometer of the health of young and often imperfect democratic systems. The example of press freedom we set in this country is an important beacon to guide other nations as they make the transition from autocratic forms of government.

Unfortunately, the free flow of information to citizens of the United States is inhibited and our open market of information is being threatened. While gathering information on a story, a journalist is sometimes required to accept information under a promise of confidentiality. Without assurance of anonymity, many conscientious citizens with evidence of wrongdoing would stay silent. Restricting the manner in which appropriate news is gathered is tantamount to restricting the information that the public has the right to hear.

After a long period when there were few clashes between the media and authorities, a disturbing new trend has developed. More than 30 reporters have recently been served subpoenas or questioned in at least four different Federal jurisdictions about their confidential sources. From 1991 to September 6, 2001, the Department of Justice issued 88 subpoenas to the media, 17 of which sought information leading to the identification of confidential sources. In fact, three journalists have been imprisoned at the request of the Department of Justice, U.S. attorneys under its supervision, or special prosecutors since 2000. As a result, the press is hobbled in performing the public service of reporting news. I fear the end result of such actions is that many whistleblowers will refuse to come forward and reporters will be unable to provide the American people with information they deserve.

Most jurisdictions in our country have recognized that confidential sources are integral to the press's role of keeping the public informed, and have provided some kind of shield so that journalists can keep secret the names of such sources. Every State and the District of Columbia, excluding Wyoming, has, by legislation or court ruling, created a privilege for reporters not to reveal their confidential sources. My own State of Indiana provides qualified reporters appropriate protection from having to reveal any such information in court.

The Federal courts of appeals, however, have an inconsistent view of this matter. Some circuits allow the privilege in one category of cases, while others have expressed skepticism about whether any privilege exists at all. It does not make sense to have a Federal system of various degrees of press freedom dependent upon where you live or who provides the subpoena. In fact, 34 State attorneys general have argued that the lack of a clear standard of Federal protection undermines state laws.

In addition, there is ambiguity between official Department of Justice rules and unofficial criteria used to secure media subpoenas. The Department of Justice guidelines also do not apply to special prosecutors or private civil litigants. There is an urgent need for Congress to state clear and concise policy guidance.

In response to this situation, 2 years ago, I was pleased to join with my colleague Congressman MIKE PENCE, and Congressman RICK BOUCHER in the House of Representatives and Senator CHRIS DODD in the Senate to introduce the Free Flow of Information Act. This legislation provides journalists with certain rights and abilities to seek sources and report appropriate information without fear of intimidation or imprisonment. The bill sets national standards which must be met before a Federal entity may issue a subpoena to a member of the news media in any Federal criminal or civil case. It sets out certain tests that civil litigants or prosecutors must meet before they can force a journalist to turn over information. Litigants or prosecutors must show, for instance, that they have tried, unsuccessfully, to get the information in other ways and that the information is critical to the case. These standards were based on Justice Department guidelines and common law standards.

Subsequently, additional protections have been added to this bill to ensure that information will be disclosed in cases where the information is critical to prevent death or bodily harm or in cases which relate to the unlawful disclosure of trade secrets. The bill also permits a reporter to be compelled to reveal the source in certain national security situations. Finally, the bill would provide protections to ensure that source information can be provided when personal health records and financial records were disclosed in violation of Federal law.

By providing the courts with a framework for compelled disclosure, our legislation promotes greater transparency of government, maintains the ability of the courts to operate effectively, and protects whistleblowers who identify government or corporate misdeeds.

It is also important to note what this legislation does not do. The legislation neither gives reporters a license to break the law, nor permits reporters to interfere with criminal investigation efforts. State shield laws have been on the books for years, and I have not seen any evidence to support a correlation between reporter privilege laws and criminal activity or threats to public safety. Furthermore, the Free Flow of Information Act does not weaken our national security. The explicit national security exception will ensure that reporters are protected while maintaining an avenue for prosecution and disclosure when considering the defense of our country. This qualified privilege has been carefully crafted to balance the distinct and important roles of both the press and law enforcement.

As ranking member of the United States Senate Foreign Relations Committee, I believe that passage of this bill would have positive diplomatic consequences. This legislation not only confirms America's Constitutional commitment to press freedom, it also advances President Bush's American foreign policy initiatives to promote and protect democracy. Our Nation always leads best when it leads by example.

Unfortunately, the press remains under siege in a number of foreign countries. For instance, Reporters Without Borders points out that 125 journalists are currently in jail around the world, with more than half of these cases in China, Cuba, and Burma. This is not good company for the United States of America. Global public opinion is always on the lookout to advertise perceived American double standards.

I would like to thank my colleague, Senator CHRIS DODD as well as MIKE PENCE and RICK BOUCHER, in the House of Representatives for their tireless work on this issue. I look forward to continuing work with each of them to protect the free flow of information.

Mr. DODD. Mr. President, I rise to join my colleague Senator LUGAR, along with Representatives BOUCHER and PENCE in the House of Representatives, in introducing the Free Flow of Information Act. This bill would protect journalists from being forced to reveal their confidential sources, not as an end in itself, but as a means to a well-informed public. I applaud the tireless efforts of the senior Senator from Indiana, Mr. LUGAR, in once again bringing this important issue to the attention of Congress and indeed the nation.

I hardly have to read the litany of grave wrongs that have been exposed because journalists called the powerful to account. And I don't have to remind you how many of those exposures relied on confidential sources. Without confidential sources, would we still be ignorant about abuse of power in the Watergate era? Without confidential sources, would Enron still be profiting from fraud? How long would torture at Abu Ghraib have persisted, if proof hadn't been provided to the press?

The free flow of information provides the American people its most meaningful check on abuses such as those. Thomas Jefferson said it best: ''If I had to make a choice, to choose the government without the press or to have the press but without the government, I will select the latter without hesitation.'' Jefferson clearly understood that a free Government cannot possibly last without a free press.

But today, we find this cornerstone of self-government facing a new threat. This threat has not come from the dictates of a dangerous government, but from the best of intentions. In a spate of recent cases, prosecutors have used subpoenas, fines, and jail time to compel journalists to reveal their anonymous sources. Judith Miller of The New York Times was jailed for 85 days for refusing to reveal a source. Two San Francisco Chronicle reporters were found in contempt of court for refusing to identify sources and hand over material related to the BALCO steroids investigation. A Rhode Island journalist was sentenced to home arrest on similar charges. Last year alone, a total of some two dozen reporters have been subpoenaed or questioned about confidential sources. They were all journalists prosecuted only for the offense of journalism.

The impact of these subpoenas on the broader issue of freedom of information is undeniable. Last summer, for instance, the editor-in-chief of Time magazine testified before the Senate Judiciary Committee. This is what he said about the fallout from the Justice Department's efforts to obtain confidential information from a Time reporter: ''Valuable sources have insisted that they no longer trusted the magazine and that they would no longer cooperate on stories. The chilling effect is obvious.''

The chilling effect is obvious. Experience has shown us that the most effective constraint on free speech need not be blatant censorship: A few cases like Ms. Miller's and the San Francisco Chronicle's, and news will begin censoring itself. We can only speculate as to how many editors and publishers put the brakes on a story for fear that it could land one of their reporters in a spider web of subpoenas, charges of contempt, and prison. When we minimize the impact of confidential sources, serious journalism is crippled. We will find our papers full of stories more and more palatable to the powerful and secretive. No one argues that that is the intention of those prosecuting these cases; but few deny that it could, in time, be their effect.

When journalists are hauled into court and threatened with imprisonment if they don't divulge their sources, we are entering dangerous territory for a democracy. The information we need to remain sovereign will be degraded; the public's right to know will be threatened; and I suggest to you that the liberties we hold dear will be threatened as well.

That is exactly why we need a Federal reporter shield. Forty-nine States and the District of Columbia have already recognized that need by enacting similar protection on the state level either through legislation or court decisions; the Free Flow of Information Act simply extends that widely recognized protection to the Federal courts.

The new version of this bill expands coverage in two significant ways. First, it will not only protect the information journalists obtain under the promise of confidentiality; it will also cover the ''work product'' of journalists as well, whether or not it was subject to that promise. And second, it no longer limits its protection to mainstream reporters; the new version also shields any person ''engaged in journalism.'' In today's expansive media environment, it would be unacceptable to deny the shield to our citizen-journalists.

Of course, the reporter shield is not absolute. The public's need to know must be weighed against other goods, and that is why the bill establishes a balancing test that takes into account ''both the public interest in compelling disclosure and the public interest in gathering news and maintaining the free flow of information.'' Specifically, the bill will not protect anonymity when disclosure of a source would prevent imminent harm to national security, imminent death or bodily harm, or the release of personal or health related information. In other words, we are balancing our right to know with our need for security, whether physical or economic. Secrecy is as necessary in extreme circumstances as it is dangerous on the whole.

It is on the idea of balance that I would like to conclude. A prosecution, whatever its individual merits, sacrifices something higher when it turns on reporters; and so those merits must be balanced against the broader harms such a prosecution can work. If a free press inexorably creates a free government, as Jefferson suggested, then the agents of that free government, prosecutors included, owe a high debt to journalism. When prosecutors threaten journalism, they have begun to renege on that debt. So I am proud to support this valuable bill, a step toward rebalancing the pursuit of justice and the diffusion of truth.

By Mr. INHOFE:

S. 1269. A bill to improve border security in the United States and for other purposes; to the Committee on the Judiciary.

Mr. INHOFE. Mr. President, I once again today introduced S. 1269, the ENFORCE Act, because this body has failed to move forward with sound immigration legislation. My bill is a strong step in the right direction to help solve our growing problem of illegal immigration.

I did this already. I did this last year. We had a chance to talk about it, but we never were able to get this up to a vote. I do want to keep this subject moving because people are not talking about this anymore. This bill focuses on securing our borders and empowering our citizens and law enforcement officers to fight the all-time high flood of illegal immigrants. There are around a million illegal aliens infiltrating our borders each year. It also addresses some of the lesser known but equally destructive exploitations of our Nation by some of these illegal immigrants.

I wish to be clear, for some reason—I am not sure why—- I have been honored over the years to speak at nationalization ceremonies. It is one of the emotional things a person can go through. When you see people coming into this country and doing it the way

they are supposed to, they learn the history. Those who have gone through the legal process know more about the history of America than the average person you run into on the street. I am very strongly in favor of legal immigration.

In 1997, the U.S. Commission on Immigration Reform stated that ''measured, legal immigration has led to create one of the world's greatest multiethnic nations.'' I agree with that statement. I also agree with their statement that when immigrants become ''Americanized,'' they help cultivate a shared commitment to ''liberty, democracy, and equal opportunity'' in our Nation. That is legal immigration. I agree with that.

However, I am quoting now from Roy Beck, executive director of Numbers USA. He stated:

A presence of 8 to 11 million illegal aliens—

I think the figure is now approximately 12 million—

in this country is a sign that this country has lost control of its borders and the ability to determine who is a member of this national community. And a country that has lost that ability increasingly loses its ability to determine the rules of its society—environmental protections, labor protection, health protections, safety protections.

Further quoting:

In fact, a country that cannot keep illegal immigration to a low level quickly ceases to be a real country, or a real community. Rather than being self-governed, such a country begins to have its destiny largely determined by citizens of other countries who manage to move in illegally.

With that being said, I cannot and I will not stand idly by and watch our great Nation collapse under the pressures of uncontrolled illegal immigration. This is a crisis, one that must be addressed aggressively. While I would not belabor the point, I will chronicle some of illegal immigration's specific threats to our Nation's vitality and how this bill will address them.

First and foremost, the issue of border security must be addressed. My bill would help ramp up border security by providing a way for civilians and retired law enforcement officers to assist the Border Patrol in stopping illegal border crossings. Keep in mind, if you are a retired Federal law enforcement officer, they have a mandatory retirement age of 57. There are many of these who would work for expenses. What we are advocating is a three-tiered system where you have the Border Patrol who are skilled the way they are today but have them fortified by this army of retired law enforcement officers and then bring in the third tier which are those which we have watched in the past that have been very effective in adding to the numbers on the border.

It is already working. It is very similar to the National Border Neighborhood Watch. I know in my State of Oklahoma it has been a very effective program. It is more eyes to watch and more talent to arrest, when necessary. A more obscure issue that also warrants reform is the legal status of what has become known as anchor babies.

To better their odds of remaining in the United States, illegal immigrants have taken advantage of a constitutional provision granting automatic citizenship to anyone born on U.S. soil. Unfortunately, by providing citizenship to these ''anchor babies,'' as they are known, our Nation rewards the illegal entry of their parents and facilities the further exploitation of our borders and national resources.

This trend has contributed to the alarming fact that the illegal immigrant population is growing faster than the birthrate of American citizens. According to the Center for Immigration Studies, based on numbers from the National Center of Health Statistics, in 2002, there were about 8.4 million illegal aliens, which represented about 3.3 percent of the total U.S. population. That same year, there were about 383,000 babies born to illegal aliens, which represents about 9.5 percent of all U.S. births in 2002.

This problem continues to grow exponentially and serves as a strong incentive for more aliens to illegally cross into our country in hopes of shortcutting citizenship requirements. Language included in the ENFORCE Act will put an end to this much exploited practice.

Another ''supposed'' obligation we face is the education of illegal aliens. Some States, such as my State of Oklahoma, allow the illegal aliens the advantage of receiving in-State tuition at our State colleges and universities. I believe it is inexcusable to give away State-subsidized educations to those who do not pay taxes. This act will address this problem by making it unlawful for illegal aliens to receive this particular handout.

The ENFORCE Act includes several provisions to halt illegal immigrants' continued exploitation of our tax laws and our Social Security benefits. One of the greatest problems in this area is illegal immigrants' abuse of the individual tax identification number. That is the ITIN program.

Currently, it so closely resembles the Social Security number that many illegal immigrants are able to use it in place of a Social Security card to bypass our tax laws or receive wrongly awarded benefits. The ENFORCE Act will require a change in the physical appearance of this particular document so its identity can no longer be mistaken for that of a Social Security number, and it will also prohibit that document from being used for identification purposes.

Additionally, my bill will require Social Security numbers to expire as soon as a person's permission to be in the United States expires. So it would expire at the same time that permission expires.

It will prohibit illegal immigrants who gain legal status from collecting Social Security benefits for the time they worked illegally in the country.

Finally, the legality of day-labor centers is a topic that must be addressed by any comprehensive immigration reform package. These day-labor centers exist within illegal immigration-friendly ''sanctuary sites'' and not just in San Francisco. Day-labor centers are State-designated and funded sites where illegal aliens congregate and wait for employers to pick them up for a day of illegal work.

One such site was approved in 2005 in Fairfax County, VA, to be paid for by taxpayer dollars. Sanctuary cities such as these enable and encourage unlawful activity by both illegal aliens and the employers who hire them. The ENFORCE Act will outlaw the creation of those particular centers.

Illegal immigrants continue to cause a myriad of problems for our country and for law-abiding citizens such as you and me. Illegal immigrants not only drain our economy through their exploitation of public services and resources, but we must not forget the national security threat posed by would-be terrorists who have entered our country illegally or remain here unlawfully by overstaying their visas.

The Center for Immigration Study says:

Even though illegal aliens make little use of welfare, from which they are generally barred, the costs of illegal immigration in terms of government expenditures for education, criminal justice, and emergency medical care are significant. Illegal immigration is straining our economy, jeopardizing our security, and burdening our education and health care systems.

So this ENFORCE Act will provide solid tools to eliminate illegal immigration and strongly enforce the existing U.S. immigration laws. The seriousness of this crisis warrants that Americans of all political stripes come together to address this problem.

One thing that is not included in this legislation that I think should be included in any kind of reform—and some of my colleagues can remember I had on the floor of the Senate the legislation making English the official language of the United States—and it is interesting that some 88 percent of the American people want this, and some 70 percent of the Hispanic population want this also. It is also interesting that there are 50 countries around the world that have English as their official language, including Ghana in West Africa and some other countries, and yet we do not have it for ourselves. But that is going to be handled separately at a different time.

History shows us that declaring ''immigration bankruptcy'' does not work. We saw that in the amnesty of 1986. Simply granting citizenship to immigrants who are currently in our country illegally is not the answer. We have to enhance our border security, hold those accountable who encourage illegal immigration, and ensure that those who violate our laws by entering our country illegally do not remain here and are not easily welcomed back.

So I am introducing that legislation, and I am going to be bringing it up at the appropriate time.

By Mr. AKAKA (for himself, Mr. KENNEDY, Mr. INOUYE, Mr. OBAMA, Mr. DURBIN, Mr. HARKIN, Mr. SALAZAR, and Mr. ISAKSON):

S. 1270. A bill to amend title IV of the Employee Retirement Income Security Act of 1974 to require the Pension Benefit Guaranty Corporation, in the case of airline pilots who are required by regulation to retire at age 60, to compute the actuarial value of monthly benefits in the form of a life annuity commencing at age 60; to the Committee on Health, Education, Labor, and Pensions.

Mr. AKAKA. Mr. President, today I am introducing the Pension Benefit Guaranty Corporation Pilots Equitable Treatment Act to ensure fair treatment of commercial airline pilot retirees. I thank my cosponsors, Senators KENNEDY, INOUYE, OBAMA, DURBIN, HARKIN, and SALAZAR. I also thank Representative GEORGE MILLER for introducing the companion legislation in the other body.

My bill corrects an injustice imposed on pilots whose pensions have been terminated and handed over to the Pension Benefit Guaranty Corporation, PBGC. This bill will lower the age requirement to receive the maximum pension benefits allowed by the PBGC to age 60 for pilots, who are mandated by the Federal Aviation Administration, FAA, to retire before age 65. With the airline industry experiencing severe financial distress, we need to enact this legislation to assist pilots whose companies have been or will be unable to continue their defined benefit pension plans. This bill will require the PBGC to take into account the fact that the pilots are required to retire at the age of 60 when calculating their benefits.

The FAA requires commercial aviation pilots to retire when they reach the age of 60. Pilots are therefore denied the maximum pension benefit administered by the PBGC because they are required to retire before the age of 65. Herein lies the problem. If pilots want to work beyond the age of 60, they have to request a waiver from the FAA. It is my understanding that the FAA has only granted these waivers for pilots working for foreign airlines that fly to and from the United States. Therefore, retired pilots whose pensions are administered by the PBGC do not receive the maximum pension guarantee because they are forced to retire at age 60.

For plans terminated in 2005, the maximum benefit for someone that retires at 65 is $45,614 a year. For those who retire at 60, the maximum is $29,649. This significant reduction in benefits puts pilots in a difficult position. Their pensions have been reduced significantly and they are prohibited from reentering their profession due to the mandatory retirement age. They are unable to go back to their former jobs. My legislation ensures that pilots are able to obtain the maximum PBGC benefit without being unfairly penalized for having to retire at 60. We must pass this bill to provide some relief for United Airlines, Aloha Airlines, US Airways, Delta, TWA, and other pilots who have had their pensions terminated and taken over by the PBGC and suffer from this wrongly imposed penalty.

In the previous Congress, this legislation was included in the Senate-passed version of the Pension Security and Transparency Act of 2005. However, this provision was not included in the conference report. I urge my colleagues to support this bill so that we can finally provide some relief for our pilots who already have suffered financially due to the termination of their pension plans.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1270

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pension Benefit Guaranty Corporation Pilots Equitable Treatment Act''.

SEC. 2. AGE REQUIREMENT FOR AIRLINE PILOTS.

(a) SINGLE-EMPLOYER PLAN BENEFITS GUARANTEED.—Section 4022(b)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1322(b)(3)) is amended by inserting at the end the following: ''If, at the time of termination of a plan under this title, regulations prescribed by the Federal Aviation Administration require an individual to separate from service as a commercial airline pilot after attaining any age before age 65, this paragraph shall be applied to an individual who is a participant in the plan by reason of such service by substituting such age for age 65.''.

(b) AGGREGATE LIMIT ON BENEFITS GUARANTEED; CRITERIA APPLICABLE.—Section 4022B(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1322b(a)) is amended by adding at the end the following: ''If, at the time of termination of a plan under this title, regulations prescribed by the Federal Aviation Administration require an individual to separate from service as a commercial airline pilot after attaining any age before age 65, this subsection shall be applied to an individual who is a participant in the plan by reason of such service by substituting such age for age 65.''.

SEC. 3. EFFECTIVE DATE.

The amendments made by this Act shall apply to benefits payable on or after the date of enactment of this Act.

By Mr. KYL:

S. 1273. A bill to amend the Internal Revenue Code of 1986 to allow permanent look-through treatment of payments between related foreign corporations; to the Committee on Finance.

Mr. KYL. Mr. President, today I am introducing legislation to make permanent a provision of our tax that was enacted in 2006 as part of the Increase Prevention and Reconciliation Act, but expires at the end of 2008. The controlled-foreign corporation (CFC) look-through provision allows U.S.-based multinational companies to better compete with foreign companies by enabling them to be more flexible in their overseas operations. In this age of global competition, I hope my colleagues will agree that the United States needs to maintain a business climate that encourages U.S.-based companies to grow and succeed. The CFC look-through provision is an important part of that effort.

For several years now, I have been encouraging my colleagues to recognize that our tax system puts many of our best U.S. employers at a competitive disadvantage as compared to foreign-based companies. Many foreign countries only impose tax on income earned within their borders; the United States taxes U.S. companies on their worldwide income.

The general rule is that income from a foreign subsidiary is not taxed by the United States until those earnings are brought back to the U.S. parent, usually in the form of a dividend. Subpart F of the Internal Revenue Code sets forth a number of exceptions to this general rule, imposing current U.S. tax, instead of allowing deferral of taxation, on subsidiary earnings generally when that income is passive in nature. One exception to the general deferral rule imposes tax on the U.S. parent when a foreign-based subsidiary receives dividends, interest, rents or royalties from another subsidiary that is located in a different country. If the two subsidiaries are in the same country, however, U.S. tax is generally deferred until the income is repatriated to the U.S. parent.

In 2005, I introduced legislation to extend this ''same-country'' treatment, the CFC look-through provision, to payments between related foreign subsidiaries that are located in different countries, and I was pleased that the 2006 tax reconciliation bill included this provision. Today, I am introducing legislation to make the CFC look-through permanent.

Today's global economy is significantly different from the environment that existed when the subpart F rules were first introduced in 1962. As the global economy has changed, the traditional model for operating a global business has changed as well. In today's world, it makes no sense to impose a tax penalty when a company wants to fund the operations of a subsidiary in one country from the active business earnings of a subsidiary in another country. For example, to operate efficiently, a U.S.-based manufacturer could establish specialized manufacturing sites, distribution hubs, and service centers. As a result, multiple related-party entities may be required to fulfill a specific customer order. Before the CFC look-through was enacted last year, U.S. tax law inappropriately increased the cost for these foreign

subsidiaries to serve their customers in a very competitive business environment by imposing current tax on these related-party payments, even though the income continues to be used in active operations in the foreign market.

In another example, financial institutions have established foreign subsidiaries with headquarters in a financial center, such as London, and branches in multiple countries in the same geographic region. This permits an efficient ''hub and spoke'' form of regional operation; however, this efficient business model made it difficult for the same-country exception to be met for payments of dividends and interest.

Before the CFC look-through was enacted, American companies were at a real and significant competitive disadvantage as compared to foreign-based companies. U.S.-based multinationals were penalized for responding to market or investment opportunities by redeploying active foreign earnings among foreign businesses conducted through multiple subsidiaries. To remove this impediment, Congress amended subpart F to provide a general exception for inter-affiliate payments of dividends, interest, rents or royalties that are generated from an active business.

Congress was right to apply look-through treatment to payments of dividends, interest, rents and royalties between subsidiaries. If the underlying earnings would not have been subject to subpart F, the payments should not be subpart F income. Look-through treatment for payments of dividends, interest, rents and royalties should be permitted as long as the payments are made out of active business, non-subpart F, income. Look-through principles are already well developed for other purposes of the Internal Revenue Code. For example, a look-through approach to the characterization of foreign income is used for purposes of calculating foreign tax credits. A consistent application of look-through principles simplifies the interaction between subpart F and the foreign tax credit rules.

If we want to keep U.S.-based multinational companies, which employ millions of workers here at home headquartered in the United States, we must modernize our tax rules so that our companies can be competitive around the globe. I urge my colleagues to cosponsor this legislation to make permanent this modest change in the law that will enhance the position of U.S.-based employers trying to succeed in competitive foreign markets.

By Mr. DURBIN:

S. 1274. A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of food for humans and pets; to the Committee on Health, Education, Labor, and Pensions.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

There being no objection, the text of the bill was ordered to be printed in the RECORD, as follows:

S. 1274

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Human and Pet Food Safety Act of 2007''.

SEC. 2. FOOD SAFETY FOR HUMANS AND PETS.

(a) ADVERSE EVENTS; INSPECTIONS; RECALL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. NOTIFICATION AND RECALL.

''(a) NOTICE TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person that has reason to believe that any food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be in violation of this Act shall immediately notify the Secretary of the identity and location of the food.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

''(b) RECALL AND CONSUMER NOTIFICATION; VOLUNTARY ACTIONS.—If the Secretary determines that food is in violation of this Act when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and that there is a reasonable probability that the food, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—

''(1) cease distribution of the food;

''(2) notify all persons—

''(A) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(B) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;

''(3) recall the food;

''(4) in conjunction with the Secretary, provide notice of the finding of the Secretary—

''(A) to consumers to whom the food was, or may have been, distributed; and

''(B) to State and local public health officials; or

''(5) take any combination of the measures described in this paragraph, as determined by the Secretary to be appropriate in the circumstances.

''(c) CIVIL AND CRIMINAL PENALTIES.—

''(1) CIVIL SANCTIONS.—

''(A) CIVIL PENALTY.—Any person that commits an act that violates the notification and recall standards under subsection (b) (including a regulation promulgated or order issued under this Act) may be assessed a civil penalty by the Secretary of not more than $10,000 for each such act.

''(B) SEPARATE OFFENSE.—Each act described in subparagraph (A) and each day during which that act continues shall be considered a separate offense.

''(2) OTHER REQUIREMENTS.—

''(A) WRITTEN ORDER.—The civil penalty described in paragraph (1) shall be assessed by the Secretary by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Secretary.

''(B) AMOUNT OF PENALTY.—Subject to paragraph (1)(A), the amount of the civil penalty shall be determined by the Secretary, after considering—

''(i) the gravity of the violation;

''(ii) the degree of culpability of the person;

''(iii) the size and type of the business of the person; and

''(iv) any history of prior offenses by the person under this Act.

''(C) REVIEW OF ORDER.—The order may be reviewed only in accordance with subsection (d).

''(3) EXCEPTION.—No person shall be subject to the penalties of this subsection—

''(A) for having received, proffered, or delivered in interstate commerce any food, if the receipt, proffer, or delivery was made in good faith, unless that person refuses to furnish (on request of an officer or employee designated by the Secretary)—

''(i) the name, address and contact information of the person from whom that person purchased or received the food;

''(ii) copies of all documents relating to the person from whom that person purchased or received the food; and

''(iii) copies of all documents pertaining to the delivery of the food to that person; or

''(B) if that person establishes a guaranty signed by, and containing the name and address of, the person from whom that person received in good faith the food, stating that the food is not adulterated or misbranded within the meaning of this Act.

''(d) JUDICIAL REVIEW.—

''(1) IN GENERAL.—An order assessing a civil penalty under subsection (c) shall be a final order unless the person—

''(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and

''(B) simultaneously serves a copy of the petition by certified mail to the Secretary.

''(2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Secretary shall file in the court a certified copy of the administrative record upon which the order was issued.

''(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

''(e) COLLECTION ACTIONS FOR FAILURE TO PAY.—

''(1) IN GENERAL.—If any person fails to pay a civil penalty assessed under subsection (c) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (d) has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute in a United States district court of competent jurisdiction a civil action to recover the amount assessed.

''(2) LIMITATION ON REVIEW.—In a civil action under paragraph (1), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to judicial review.

''(f) PENALTIES PAID INTO ACCOUNT.—The Secretary—

''(1) shall deposit penalties collected under this section in an account in the Treasury; and

''(2) may use the funds in the account, without further appropriation or fiscal year limitation—

''(A) to carry out enforcement activities under food safety law; or

''(B) to provide assistance to States to inspect retail commercial food establishments, such as an establishment that holds, stores, or transports food or food ingredients, or

other food or firms under the jurisdiction of State food safety programs.

''(g) DISCRETION OF THE SECRETARY TO PROSECUTE.—Nothing in this section, section 418, or section 419 requires the Secretary to report for prosecution, or for the commencement of an action, the violation of this Act in a case in which the Secretary finds that the public interest will be adequately served by the assessment of a civil penalty under this section.

''(h) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section may be in addition to, and not exclusive of, other remedies that may be available.

''SEC. 418. MANDATORY RECALL ACTION.

''(a) MANDATORY ACTIONS.—If a person referred to in section 417(b) refuses to or does not adequately carry out the actions described in that section within the time period and in the manner prescribed by the Secretary, the Secretary shall—

''(1) have authority to control and possess the food, including ordering the shipment of the food from a food establishment, such as an establishment that holds, stores, or transports food or food ingredients, to the Secretary—

''(A) at the expense of such food establishment; or

''(B) in an emergency (as determined by the Secretary), at the expense of the Secretary; and

''(2) by order, require, as the Secretary determines to be necessary, the person to immediately—

''(A) cease distribution of the food; and

''(B) notify all persons—

''(i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(ii) if the food has been distributed, transported, or sold, to immediately cease distribution of the food.

''(b) NOTIFICATION TO CONSUMERS BY SECRETARY.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1)—

''(1) to consumers to whom the food was, or may have been, distributed; and

''(2) to State and local public health officials.

''(c) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under section 417(b)(2) or subsection (a)(2)(B) of this section shall immediately cease distribution of the food.

''(d) AVAILABILITY OF RECORDS TO SECRETARY.—Each person referred to in section 417 that processed, distributed, or otherwise handled food shall make available to the Secretary information necessary to carry out this subsection, as determined by the Secretary, regarding—

''(1) persons that processed, distributed, or otherwise handled the food; and

''(2) persons to which the food has been transported, sold, distributed, or otherwise handled.

''(e) INFORMAL HEARINGS ON ORDERS.—

''(1) IN GENERAL.—The Secretary shall provide any person subject to an order under subsection (a) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.

''(2) SCOPE OF THE HEARING.—In a hearing under paragraph (1), the Secretary shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.

''(f) POST-HEARING RECALL ORDERS.—

''(1) AMENDMENT OF ORDER.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that there is a reasonable probability that the food that is the subject of an order under subsection (a), if consumed, would present a threat to the public health, the Secretary, as the Secretary determines to be necessary, may—

''(A) amend the order to require recall of the food or other appropriate action;

''(B) specify a timetable in which the recall shall occur;

''(C) require periodic reports to the Secretary describing the progress of the recall; and

''(D) provide notice of the recall to consumers to whom the food was, or may have been, distributed.

''(2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

''(g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section shall be in addition to, and not exclusive of, other remedies that may be available.

''SEC. 419. FOREIGN INSPECTIONS; IMPORTS.

''(a) AUTHORITY TO INSPECT.—The Secretary shall have the authority to visit any foreign country that imports to the United States human or pet food. Such a visit shall be for the purpose of auditing the food safety or pet food programs of such foreign country or to conduct investigations in the event that a food or ingredient of a food is found to violate this Act.

''(b) IMPORTS.—

''(1) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall establish a system under which a foreign government or foreign manufacturer, importer, distributor, or retailer that seeks to import food to the United States shall submit a request for certification to the Secretary.

''(2) CERTIFICATION STANDARD.—A foreign government or foreign manufacturer, importer, distributor, or retailer requesting a certification to import food to the United States shall demonstrate, in a manner determined appropriate by the Secretary, that food produced under the supervision of a foreign government or by the foreign manufacturer, importer, distributor, or retailer has met standards for food safety, inspection, labeling, and consumer protection that are at least equivalent to standards applicable to food produced in the United States.

''(3) CERTIFICATION APPROVAL.—

''(A) REQUEST BY FOREIGN GOVERNMENT.—Prior to granting the certification request of a foreign government, the Secretary shall review, audit, and certify the food safety program of a requesting foreign government (including all statutes, regulations, and inspection authority) as at least equivalent to the food safety program in the United States, as demonstrated by the foreign government.

''(B) REQUEST BY FOREIGN ESTABLISHMENT.—Prior to granting the certification request of a foreign manufacturer, importer, distributor, or retailer that seeks to import food to the United States, the Secretary shall certify, based on an onsite inspection, the food safety programs and procedures of a requesting foreign firm as at least equivalent to the food safety programs and procedures of the United States.

''(4) LIMITATION.—A foreign government or foreign manufacturer, importer, distributor, or retailer approved by the Secretary to import food to the United States under this section shall be certified to export only the approved food products to the United States for a period not to exceed 5 years.

''(5) WITHDRAWAL OF CERTIFICATION.—The Secretary may withdraw certification of any food from a foreign government or foreign manufacturer, importer, distributor, or retailer that seeks to import food to the United States—

''(A) if such food is linked to an outbreak of human illness;

''(B) following an investigation by the Secretary that finds that the food safety programs and procedures of the foreign government or foreign manufacturer, importer, distributor, or retailer are no longer equivalent to the food safety programs and procedures in the United States; or

''(C) following a refusal to allow United States officials to conduct such audits and investigations as may be necessary to fulfill the requirements under this section.

''(6) RENEWAL OF CERTIFICATION.—The Secretary shall audit a foreign government and a foreign manufacturer, importer, distributor, or retailer that seeks to import food to the United States at least every 5 years to ensure the continued compliance with the standards set forth in this section.

''(7) REQUIRED ROUTINE INSPECTION.—The Secretary shall routinely inspect food and food animals (via a physical examination) before it enters the United States to ensure that it is—

''(A) safe;

''(B) labeled as required for food produced in the United States; and

''(C) otherwise meets requirements under this Act.

''(8) RECORDS INSPECTION.—

''(A) IN GENERAL.—The responsible party or importer shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

''(B) DEFINTIONS.—For purposes of this paragraph—

''(i) the term 'authorized person' means an officer or employee of the Department of Health and Human Services, who has—

''(I) appropriate credentials, as determined by the Secretary; and

''(II) been duly designated by the Secretary to have access to the records required under this section; and

''(ii) the term 'responsible party' means, with respect to an article of food, any person responsible for the manufacturing, processing, packaging, or holding for such food for consumption in the United States.

''(9) ENFORCEMENT.—The Secretary is authorized to—

''(A) deny importation of food from any foreign government that does not permit United States officials to enter the foreign country to conduct such audits and inspections as may be necessary to fulfill the requirements under this section;

''(B) deny importation of food from any foreign government or foreign manufacturer, importer, distributor, or retailer that does not consent to an investigation by the Administration when food from that foreign country or foreign firm is linked to a foodborne illness outbreak or is otherwise found to be adulterated or mislabeled; and

''(C) promulgate rules and regulations to carry out the purposes of this section, including setting terms and conditions for the destruction of products that fail to meet the standards of this Act.

''(10) DETENTION AND SEIZURE.—Any food imported for consumption in the United States may be detained, seized, or condemned pursuant to section 418.''.

SEC. 3. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food shall—

(1) work with companies, relevant professional associations, and other organizations

to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. 4. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to feed, pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify contaminations of the pet food supply and outbreaks of illness from pet food. In establishing such system, the Secretary shall—

(A) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(B) consult with relevant professional associations and private sector veterinary hospitals; and

(C) work with Health Alert Networks and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out paragraph (1) such sums as may be necessary.

SEC. 5. SENSE OF THE SENATE.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion pets caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic loses to manufactures and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food, without adequate monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that—

(A) from 2003 to the present, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional Food and Drug Administration inspectors are required if we are to improve Food and Drug Administration's ability to safeguard the food supply of the United States; and

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements, including memoranda of understanding, with the trading partners of the United States with respect to food safety.

SEC. 6. ANNUAL REPORT TO CONGRESS.

The Secretary of Health and Human Service shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products imported into the United States, aggregated by country, and type of food, if any;

(2) a listing of the number of inspectors of imported food products and the number of inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement mechanisms used to follow-up on such findings and violations.

SUBMITTED RESOLUTIONS

SENATE CONCURRENT RESOLUTION 30—URGING ALL SIDES TO THE CURRENT POLITICAL CRISIS IN UKRAINE TO ACT RESPONSIBLY AND USE DIALOGUE TO RESOLVE THE CRISIS AND ENSURE A FREE AND TRANSPARENT DEMOCRATIC SYSTEM IN UKRAINE BASED ON THE RULE OF LAW

Mr. DODD submitted the following concurrent resolution; which was referred to the Committee on Foreign Relations:

S. CON. RES. 30

Resolved by the Senate (the House of Representatives concurring), That Congress—

(1) acknowledges and welcomes the strong relationship formed between the United States and Ukraine since the restoration of Ukraine's independence in 1991;

(2) urges all sides to the current political crisis in Ukraine to act responsibly and use dialogue to resolve the crisis;

(3) urges all sides to adhere to the rule of law and resolve disputes in a peaceful manner consistent with Ukraine's democratic values and national interest, in keeping with its commitments as a member of the Organization for Security and Cooperation in Europe (OSCE);

(4) expresses strong and continuing support for the efforts of the Ukrainian people to establish a full democracy, the rule of law, and respect for human rights;

(5) pledges its continued assistance to the strengthening of a free and transparent democratic system in Ukraine based on the rule of law and the continued development of a free market economy in Ukraine; and

(6) reaffirms its commitment to Ukraine's independence, sovereignty and territorial integrity, and assumption of Ukraine's rightful place as a full member of the international community of democracies.

AMENDMENTS SUBMITTED AND PROPOSED

SA 1008. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table.

SA 1009. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1010. Mr. COCHRAN (for himself, Mr. CARPER, Mr. NELSON, of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra.

SA 1011. Ms. STABENOW (for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL) submitted an amendment intended to be proposed by her to the bill S. 1082, supra.

SA 1012. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1013. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1014. Mr. VITTER submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1015. Mr. HAGEL (for himself and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1016. Mr. SPECTER submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1017. Mr. GREGG (for himself and Mr. COLEMAN) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1018. Mr. DEMINT (for himself, Mr. INHOFE, Mr. BROWNBACK, Mr. MARTINEZ, Mr. VITTER, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, supra.

SA 1019. Mr. CASEY (for himself and Mr. SPECTER) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1020. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1022. Mr. DURBIN (for himself, Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, Mr. KOHL, Ms. CANTWELL, Mr. SCHUMER, Mr. BIDEN, Mr. NELSON, of Florida, and Mr. CASEY) proposed an amendment to the bill S. 1082, supra.

SA 1023. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1024. Mr. SALAZAR submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1025. Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY) proposed an amendment to the bill S. 1082, supra.

SA 1026. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1027. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1028. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr. KOHL, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1029. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1030. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1031. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1032. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

SA 1033. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, supra; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 1008. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike section 252 and insert the following:

SEC. ___. MARIJUANA SMOKED BY PATIENTS.

(a) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary of Health and Human Services shall conduct an evaluation of the manufacture, distribution, and use of marijuana in States that have enacted laws legalizing, decriminalizing, or otherwise allowing the use of marijuana for purported medical use to determine—

(A) whether such activity is taking place in violation of any provision of Federal law for which the Department of Health of Human Services is responsible; and

(B) whether such marijuana activities are taking place in violation of any provision of the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that is designed to ensure the safety and effectiveness of drugs used by the American public.

(2) REPORT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report concerning the findings of the evaluation conducted under paragraph (1).

(b) DETERMINATION OF EFFECTIVENESS.—Not later than 30 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall, based on available scientific data, make a determination, and disclose such determination to the general public, concerning—

(1) whether or not smoked marijuana is a safe or effective treatment for any medical condition; and

(2) the adverse impact to human health, both physician and mental, as a result of smoking marijuana.

SA 1009. Mr. HATCH submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title II, insert the following:

Subtitle ___Antibiotic Safety and Innovation

SEC. 2___. DEVELOPMENT OF ANTIMICROBIALS.

(a) INCENTIVES FOR DEVELOPMENT OF NEW ANTIBIOTICS AND NEW ANTIBIOTIC USES.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(r)(1) Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an approved application described in paragraph (2) may elect to receive, with respect to the drug—

''(A)(i) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F); and

''(ii) the 5-year exclusivity period referred to under subsection (c)(3)(E)(ii) and under subsection (j)(5)(F)(ii); or

''(B) a patent term extension under section 156 of title 35, United States Code.

''(2) An application described under this paragraph is an application for marketing submitted under this section after the date of enactment of this subsection in which—

''(A) the drug that is the subject of the application contains an antibiotic drug; and

''(B) such antibiotic drug was the subject of an application received by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

''(3) Paragraph (1) shall not be construed to entitle a drug that is the subject of an approved application described in paragraph (2) for any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1).''.

(b) BIOEQUIVALENCE TO LISTED ANTIBIOTIC DRUG.—Section 505(j)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended by adding at the end the following:

''(D) Notwithstanding any other provision of this subsection, an oral antibiotic drug that is not intended to be absorbed into the bloodstream shall be considered to be bioequivalent to a listed antibiotic drug only if—

''(i) clinical trials do not show a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness; or

''(ii) the Secretary has—

''(I) established alternative, scientifically valid methods that are reasonably expected to detect a significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness;

''(II) developed the alternative, scientifically valid methods described in subclause (I) through notice and comment rulemaking in accordance with section 553 of title 5, United States Code; and

''(III) determined that, based on the alternative, scientifically valid methods described in subclauses (I) and (II), there is no significant difference between the antibiotic drug and the listed antibiotic drug in safety and effectiveness.''.

(c) PUBLIC MEETING.—The Commissioner of Food and Drugs shall convene a public meeting and, if appropriate, issue guidance regarding which serious and life-threatening infectious diseases, such as diseases due to gram-negative bacteria and other diseases due to antibiotic-resistant bacteria, potentially qualify for available grants and contracts under subsection (a) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(a)) or other incentives for development.

(d) GRANTS AND CONTRACTS FOR THE DEVELOPMENT OF ORPHAN DRUGS.—Subsection (c) of section 5 of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended to read as follows:

''(c) For grants and contracts under subsection (a), there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2007, and $35,000,000 for each subsequent fiscal year.''.

SEC. 2___. ESTABLISHMENT OF ANTIMICROBIAL BREAKPOINTS.

(a) DEFINITION.—In this section, the term ''antimicrobial breakpoint'' means specific values which characterize bacteria as clinically susceptible, intermediate, or resistant to the drug (or drugs) tested, such as Minimum Inhibitory Concentrations (MICs) or zones of inhibitions.

(b) ESTABLISHMENT OF BREAKPOINTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall direct the Commissioner of Food and Drugs to establish and periodically update antimicrobial breakpoints.

(2) REVIEW AND UPDATE.—Antimicrobial breakpoints shall be reviewed and updated as necessary pursuant to recommendations from the Antimicrobial Resistance Task Force and in consultation with the Centers for Disease Control and Prevention, or more frequently upon the discretion of the Commissioner of Food and Drugs, but in no case less than once every 5 years.

(c) PUBLIC AVAILABILITY.—The Secretary shall direct the Commissioner of Food and Drugs to make antimicrobial breakpoints publicly available within 30 days of the date of establishment and any update under this section.

(d) ADVISORY ORGANIZATIONS.—The Commissioner of Food and Drugs may contract with an organization or organizations to aid in the establishment of antimicrobial breakpoints under this section in a manner not inconsistent with the Federal Advisory Committee Act (5 U.S.C. App.). The Commissioner of Food and Drugs shall make the final determination regarding establishments of antimicrobial breakpoints under this section.

SEC. 2___. EXCLUSIVITY OF CERTAIN DRUGS CONTAINING ENANTIOMERS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S. C. 355), as amended by this subtitle, is amended by adding at the end the following:

''(s) DRUGS CONTAINING ENANTIOMERS.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the single enantiomer shall not be considered the same active ingredient contained in the approved racemic drug, if—

''(1)(A) the single enantiomer has not been previously approved as an active ingredient except in the approved racemic drug; and

''(B) the application submitted under subsection (b) for the drug containing the single enantiomer includes full reports of investigations described in subsection (b)(1)(A) which do not rely on any investigations that are part of the application submitted under subsection (b) for approval of the approved racemic drug; and

''(2)(A) the application submitted under subsection (b) for the drug containing the single enantiomer is not submitted for approval of a use—

''(i) in a therapeutic area in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved; or

''(B) in the case of an antibiotic drug, such drug is demonstrated through well-controlled clinical trials to be safe and effective for a use for which the racemic drug has not been approved and for which no other enantiomer of the racemic drug has been previously approved.''.

SA 1010. Mr. COCHRAN (for himself, Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the amendment, add the following:

SEC. ___. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

SA 1011. Ms. STABENOW (for herself, Mr. THUNE, Mr. LOTT, Mr. BROWN, and Mr. KOHL) submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the appropriate place, insert the following:

SEC. ___. CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is amended by adding at the end the following:

''(r) CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—

''(1) IN GENERAL.—

''(A) NO DELAY OF CONSIDERATION OR APPROVAL.—

''(i) IN GENERAL.—With respect to a pending application submitted under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, clauses (ii) and (iii) shall apply.

''(ii) NO DELAY OF CONSIDERATION.—The receipt of a petition is not just cause to delay consideration of an application submitted under subsection (b)(2) or (j) and consideration of a petition described in clause (i) shall be separate and apart from the review of an application submitted under either such subsection.

''(iii) NO DELAY OF APPROVAL WITHOUT DETERMINATION.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition described in clause (i) is reviewed and considered unless the Secretary determines, not later than 30 days after the submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A)(iii) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making such determination, the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement shall include a summary of the petition and comments and supplements, the specific substantive issues that the petition raises which need to be considered prior to approving a pending application submitted under subsection (b)(2) or (j), and any clarifications and additional data that is needed by the Secretary to promptly review the petition.

''(ii) Not later than 10 days after making such determination, the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(2) TIMING OF FINAL AGENCY ACTION ON PETITIONS.—

''(A) IN GENERAL.—Notwithstanding a determination made by the Secretary under paragraph (1)(A)(iii), the Secretary shall take final agency action with respect to a petition not later than 180 days of submission of that petition unless the Secretary determines, prior to the date that is 180 days after the date of submission of the petition, that a delay is necessary to protect the public health.

''(B) DETERMINATION OF DELAY.—With respect to a determination by the Secretary under subparagraph (A) that a delay is necessary to protect the public health the following shall apply:

''(i) Not later than 5 days after making the determination under subparagraph (A), the Secretary shall publish on the Internet website of the Food and Drug Administration a detailed statement providing the reasons underlying the determination. The detailed statement should include the state of the review of the petition, the specific outstanding issues that still need to be resolved, a proposed timeframe to resolve the issues, and any additional information that has been requested by the Secretary of the petitioner or needed by the Secretary in order to resolve the petition and not further delay an application filed under subsection (b)(2) or (j).

''(ii) Not later than 10 days after making the determination under subparagraph (A), the Secretary shall provide notice to the sponsor of the pending application submitted under subsection (b)(2) or (j) and provide an opportunity for a meeting with appropriate staff as determined by the Commissioner to discuss the determination.

''(3) VERIFICATIONS.—

''(A) PETITIONS FOR REVIEW.—The Secretary shall not accept a petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; and (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition and the signature of the petitioner inserted in the first and second blank space, respectively.

''(B) SUPPLEMENTAL INFORMATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and that the subject document is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents. I further certify that the information upon which I have based the action requested herein first became known to me on or about _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to submit this information or its contents: _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the submission of such document and the signature of the petitioner inserted in the first and second blank space, respectively.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITION.—The Secretary shall annually submit to the Congress a report that specifies—

''(A) the number of applications under subsection (b)(2) and (j) that were approved during the preceding 1-year period;

''(B) the number of petitions that were submitted during such period;

''(C) the number of applications whose effective dates were delayed by petitions during such period and the number of days by which the applications were so delayed; and

''(D) the number of petitions that were filed under this subsection that were deemed by the Secretary under paragraph (1)(A)(iii) to require delaying an application under subsection (b)(2) or (j) and the number of days by which the applications were so delayed.

''(5) EXCEPTION.—This subsection does not apply to a petition that is made by the sponsor of the application under subsection (b)(2) or (j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) REPORT BY INSPECTOR GENERAL.—The Office of Inspector General of the Department of Health and Human Services shall issue a report not later than 2 years after the

date of enactment of this subsection evaluating evidence of the compliance of the Food and Drug Administration with the requirement that the consideration by the Secretary of petitions that do not raise public health concerns remain separate and apart from the review and approval of an application submitted under subsection (b)(2) or (j).

''(7) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.''.

SA 1012. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. AUTHORIZATION OF APPROPRIATIONS FOR THE OFFICE OF GENERIC DRUGS.

Notwithstanding section 736(b) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(b) of this Act), the Secretary of Health and Human Services shall allocate $20,000,000 of the user fees generated by section 736(a) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(a) of this Act), for each fiscal year beginning with fiscal year 2009 and ending with fiscal year 2012, to the Office of Generic Drugs of the Food and Drug Administration, for the sole purpose of reviewing and approving abbreviated new drug applications.

SA 1013. Mr. VITTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. OFFICE OF GENERIC DRUGS.

(a) FINDINGS.—Congress makes the following findings:

(1) More than $100,000,000,000 in blockbuster brand pharmaceutical products will lose patent protection between April 2007 and 2010. As a result, more applications for generic versions of these products will be filed with the Office of Generic Drugs of the Food and Drug Administration.

(2) The staff of the Office of Generic Drugs is backlogged. Approximately 800 generic drug applications are pending review as of April 2007.

(3) The workload of the Office of Generic Drugs has increased by 36 percent since 2004, yet the Office has the same budget and the same number of staff.

(4) The workload of the Office of Generic Drugs also has increased due to the filing of citizen petitions by brand companies designed to delay generic drug approvals.

(5) A modest investment in the Office of Generic Drugs, such as $15,000,000, would help to make more affordable medicines available in a timely manner to consumers and public and private health care purchasers, who would save billions of dollars.

(6) Those savings also would enable the Federal Government to reach more Americans through important health care initiatives, such as Medicare, Medicaid, and programs to improve children's health care, assist the chronically ill, and fight HIV/AIDS.

(b) AUTHORIZATION OF APPROPRIATIONS.—Notwithstanding section 736(b) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(b) of this Act), the Secretary of Health and Human Services shall allocate $20,000,000 of the user fees generated by section 736(a) of the Federal Food, Drug, and Cosmetic Act (as amended by section 103(a) of this Act), for each fiscal year beginning with fiscal year 2009 and ending with fiscal year 2012, to the Office of Generic Drugs of the Food and Drug Administration, for the sole purpose of reviewing and approving abbreviated new drug applications.

SA 1014. Mr. VITTER submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in the amendment, insert the following:

SEC. ___. COUNTERFEIT-RESISTANT TECHNOLOGIES FOR PRESCRIPTION DRUGS.

(a) REQUIRED TECHNOLOGIES.—The Secretary of Health and Human Services shall require that the packaging of any prescription drug incorporate—

(1) radio frequency identification (RFID) tagging technology, or similar trace and track technologies that have an equivalent function;

(2) tamper-indicating technologies; and

(3) blister security packaging when possible.

(b) USE OF TECHNOLOGIES.—

(1) AUTHORIZED USES.—The Secretary shall require that technologies described in subsection (a)(1) be used exclusively to authenticate the pedigree of prescription drugs, including by—

(A) implementing inventory control;

(B) tracking and tracing prescription drugs;

(C) verifying shipment or receipt of prescription drugs;

(D) authenticating finished prescription drugs; and

(E) electronically authenticating the pedigree of prescription drugs.

(2) PRIVACY PROTECTION.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any information that may be used to identify a health care practitioner or the prescription drug consumer.

(3) PROHIBITION AGAINST ADVERTISING.—The Secretary shall prohibit technologies required by subsection (a)(1) from containing or transmitting any advertisement or information about prescription drug indications or off-label prescription drug uses.

(c) RECOMMENDED TECHNOLOGIES.—The Secretary shall encourage the manufacturers and distributors of prescription drugs to incorporate into the packaging of such drugs, in addition to the technologies required under subsection (a), overt optically variable counterfeit-resistant technologies that—

(1) are visible to the naked eye, providing for visual identification of prescription drug authenticity without the need for readers, microscopes, lighting devices, or scanners;

(2) are similar to technologies used by the Bureau of Engraving and Printing to secure United States currency;

(3) are manufactured and distributed in a highly secure, tightly controlled environment; and

(4) incorporate additional layers of nonvisible covert security features up to and including forensic capability.

(d) STANDARDS FOR PACKAGING.—

(1) MULTIPLE ELEMENTS.—For the purpose of making it more difficult to counterfeit the packaging of prescription drugs, the Secretary shall require manufacturers of prescription drugs to incorporate the technologies described in paragraphs (1), (2), and (3) of subsection (a), and shall encourage manufacturers and distributors of prescription drugs to incorporate the technologies described in subsection (c), into multiple elements of the physical packaging of the drugs, including—

(A) blister packs, shrink wrap, package labels, package seals, bottles, and boxes; and

(B) at the item level.

(2) LABELING OF SHIPPING CONTAINER.—Shipments of prescription drugs shall include a label on the shipping container that incorporates the technologies described in subsection (a)(1), so that members of the supply chain inspecting the packages will be able to determine the authenticity of the shipment. Chain of custody procedures shall apply to such labels and shall include procedures applicable to contractual agreements for the use and distribution of the labels, methods to audit the use of the labels, and database access for the relevant governmental agencies for audit or verification of the use and distribution of the labels.

(e) PENALTY.—A prescription drug is deemed to be misbranded for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) if the packaging or labeling of the drug is in violation of a requirement or prohibition applicable to the drug under subsection (a), (b), or (d).

(f) TRANSITIONAL PROVISIONS; EFFECTIVE DATES.—

(1) NATIONAL SPECIFIED LIST OF SUSCEPTIBLE PRESCRIPTION DRUGS.—

(A) INITIAL PUBLICATION.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall publish in the Federal Register a list, to be known as the National Specified List of Susceptible Prescription Drugs, consisting of not less than 30 of the prescription drugs that are most frequently subject to counterfeiting in the United States (as determined by the Secretary).

(B) REVISION.—Not less than annually through the end of calendar year 2010, the Secretary shall review and, as appropriate, revise the National Specified List of Susceptible Prescription Drugs. The Secretary may not revise the List to include fewer than 30 prescription drugs.

(2) EFFECTIVE DATES.—The Secretary shall implement the requirements and prohibitions of subsections (a), (b), and (d)—

(A) with respect to prescription drugs on the National Specified List of Susceptible Prescription Drugs, beginning not later than the earlier of—

(i) 1 year after the initial publication of such List; or

(ii) December 31, 2008; and

(B) with respect to all prescription drugs, beginning not later than December 31, 2011.

(3) AUTHORIZED USES DURING TRANSITIONAL PERIOD.—In lieu of the requirements specified in subsection (b)(1), for the period beginning on the effective date applicable under paragraph (2)(A) and ending on the commencement of the effective date applicable under paragraph (2)(B), the Secretary shall require that technologies described in subsection (a)(1) be used exclusively to verify the authenticity of prescription drugs.

(g) DEFINITIONS.—In this Act:

(1) The term ''pedigree''—

(A) means the history of each prior sale, purchase, or trade of the prescription drug involved to a distributor or retailer of the drug (including the date of the transaction and the names and addresses of all parties to the transaction); and

(B) excludes information about the sale, purchase, or trade of the drug to the drug consumer.

(2) The term ''prescription drug'' means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(3) The term ''Secretary'' means the Secretary of Health and Human Services.

SA 1015. Mr. HAGEL (for himself and Mrs. CLINTON) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. LUNG CANCER COMPUTED TOMOGRAPHY ASSESSMENT AND INTERIM QUALITY STANDARDS.

Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains—

(1) an assessment of the number, quality, charges, and capabilities of sites offering computed tomography scanning for the diagnosis of lung cancer;

(2) interim quality standards for computed tomography scanning for the diagnosis of lung cancer which incorporate the protocol established by the International Early Lung Cancer Action Program and contained in the document dated October 20, 2006 entitled ''International Early Lung Cancer Action Program: Enrollment and Screening Protocol''; and

(3) recommendations, including legislative recommendations if appropriate, for the establishment of lung cancer diagnostic centers, as practicable, to collect and analyze the data as recommended under the protocol described in paragraph (2) in order to continue and accelerate research into the early detection, diagnosis, and treatment of lung cancer.

SA 1016. Mr. SPECTER submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place in the bill, insert the following:

SEC. ___. NATIONAL CENTERS FOR PHARMACEUTICAL INNOVATION.

Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter ___—Establishment of the National Centers for Pharmaceutical Innovation

''SEC. ___1. ESTABLISHMENT OF THE CENTERS.

''(a) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Secretary, shall establish through competitive selection not more than 5 university-based National Centers for Pharmaceutical Innovation (referred to in this subchapter as the 'Centers').

''(b) PURPOSE OF CENTERS.—The purpose of the Centers is to advance the Food and Drug Administration's Critical Path Initiative, as well as subsequent efforts, to modernize medical pharmaceutical product development by—

''(1) designing methodologies to dramatically increase the speed at which new drugs enter the market while significantly reducing the cost of such process;

''(2) developing new technological tools to speed the creation of safer, more effective drugs targeted at individuals;

''(3) assisting the Food and Drug Administration with drug therapy-monitoring programs to look for adverse consequences utilizing medicines;

''(4) expanding the quality and number of professionals trained in translational medicine, translational therapeutics, and the manufacture of pharmaceutical and biotechnology products; and

''(5) introducing new technologies to improve the manufacture of pharmaceutical and biotechnology products.

''SEC. ___2. CRITERIA FOR SELECTION.

''The Commissioner of Food and Drugs, in consultation with the Secretary, shall select the Centers from among qualified university or university consortium applicants on the basis of key factors in pharmaceutical product development, safety, and manufacturing technology, including—

''(1) whether the applicant has established graduate training programs that integrate the elements of translational therapeutics, including basic and clinical pharmacology, pharmaceutical science, including pharmacokinetic modeling, analytical technologies, genomics and proteomics, pharmacoepidemiology, informatics, and statistics;

''(2) demonstration of extensive experience in the development and evaluation of medicines through drug approval to the post-marketing process;

''(3) scientific programs in translational therapeutics and pharmaceutical science designed to hasten the personalization of medicine;

''(4) proficiencies in pharmaceutical and biotechnology science and engineering, including therapy development and manufacturing; and

''(5) other factors that the Commissioner of Food and Drugs determines appropriate.

''SEC. ___3. AUTHORIZATION OF APPROPRIATIONS.

''There are authorized to be appropriated to carry out this subchapter such sums as may be necessary for each of the fiscal years 2008 through 2013.''.

SA 1017. Mr. GREGG (for himself and Mr. COLEMAN) submitted an amendment intended to be proposed to amendment SA 990 submitted by Mr. DORGAN (for himself, Ms. SNOWE,, Mr. GRASSLEY, Mr. MCCAIN, Ms. STABENOW, Mr. NELSON of Florida, Mr. PRYOR, Mr. SANDERS, Mr. WHITEHOUSE, and Mrs. MCCASKILL) to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike sections 7 and 8 of the amendment and insert the following:

SEC. 7. INTERNET PHARMACIES.

(a) INTERNET PHARMACIES.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 510 the following:

''SEC. 511. INTERNET PHARMACIES.

''(a) DEFINITIONS.—In this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) DESIGNATED PAYMENT SYSTEM.—

''(A) IN GENERAL.—The term 'designated payment system' means a system used by a person described in subparagraph (B) to effect a credit transaction, electronic fund transfer, or money transmitting service that the Board determines, by regulation or order, is regularly used in connection with, or to facilitate restricted transactions.

''(B) PERSONS DESCRIBED.—A person referred to in subparagraph (A) is—

''(i) a creditor;

''(ii) a credit card issuer;

''(iii) a financial institution;

''(iv) an operator of a terminal at which an electronic fund transfer may be initiated;

''(v) a money transmitting business; or

''(vi) a participant in an international, national, regional, or local network constructed primarily to effect a credit transaction, electronic fund transfer, or money transmitting service.

''(3) FEDERAL FUNCTIONAL REGULATOR.—The term 'Federal functional regulator' has the meaning given the term in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809).

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that offers to dispense or dispenses in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(5) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(6) RESTRICTED TRANSACTION.—The term 'restricted transaction' means a transaction or transmittal, on behalf of a individual who places an unlawful Internet pharmacy request to any person engaged in the operation of an unlicensed Internet pharmacy, of—

''(A) credit, or the proceeds of credit, extended to or on behalf of the individual for the purpose of the unlawful Internet request (including credit extended through the use of a credit card);

''(B) an electronic fund transfer or funds transmitted by or through a money transmitting business, or the proceeds of an electronic fund transfer or money transmitting service, from or on behalf of the individual for the purpose of the unlawful Internet request;

''(C) a check, draft, or similar instrument which is drawn by or on behalf of the individual for the purpose of the unlawful Internet request and is drawn on or payable at or through any financial institution; or

''(D) the proceeds of any other form of financial transaction (identified by the Board by regulation) that involves a financial institution as a payor or financial intermediary on behalf of or for the benefit of the individual for the purpose of the unlawful Internet request.

''(7) TREATING PROVIDER.—The term 'treating provider' means a health care provider licensed in the United States who is authorized to prescribe medications and who—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual, portions of which may be conducted by other health professionals;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(8) UNLAWFUL INTERNET PHARMACY REQUEST.—The term 'unlawful Internet pharmacy request' means the request, or transmittal of a request, made to an unlicensed Internet pharmacy for a prescription drug by mail (including a private carrier), facsimile, telephone, or electronic mail, or by a means that involves the use, in whole or in part, of the Internet.

''(9) UNLICENSED INTERNET PHARMACY.—The term 'unlicensed Internet pharmacy' means an Internet pharmacy that is not licensed under this section.

''(10) OTHER DEFINITIONS.—

''(A) BOARD.—The term 'Board' means the Board of Governors of the Federal Reserve System.

''(B) CREDIT; CREDITOR; CREDIT CARD.—The terms 'credit', 'creditor', and 'credit card' have the meanings given the terms in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

''(C) ELECTRONIC FUND TRANSFER.—The term 'electronic fund transfer'—

''(i) has the meaning given the term in section 903 of the Electronic Fund Transfer Act (15 U.S.C. 1693a); and

''(ii) includes any fund transfer covered under article 4A of the Uniform Commercial Code, as in effect in any State.

''(D) FINANCIAL INSTITUTION.—The term 'financial institution'—

''(i) has the meaning given the term in section 903 of the Electronic Transfer Fund Act (15 U.S.C. 1693a); and

''(ii) includes a financial institution (as defined in section 509 of the Gramm-Leach-Bliley Act (15 U.S.C. 6809)).

''(E) MONEY TRANSMITTING BUSINESS; MONEY TRANSMITTING SERVICE.—The terms 'money transmitting business' and 'money transmitting service' have the meanings given the terms in section 5330(d) of title 31, United States Code.

''(b) IN GENERAL.—An Internet pharmacy may only dispense or offer to dispense a prescription drug to a person in the United States in accordance with this section.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—An Internet pharmacy shall be licensed by the Secretary in accordance with this section prior to offering to dispense or dispensing a prescription drug to an individual.

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy whose principal place of business is located outside the United States, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(cc) the Internet pharmacy expressly and affirmatively agrees to provide and maintain an agent for service of process in the United States;

''(dd) the Internet pharmacy expressly and affirmatively agrees to be subject to the jurisdiction of the United States and any of its States or territories where it engages in commerce; and

''(ee) the Internet pharmacy agrees to affix to each shipping container of drugs to be shipped in the United States such markings as the Secretary determines to be necessary to identify that the shipment is from a licensed Internet pharmacy, which may include anticounterfeiting or track-and-trace technologies;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Internet pharmacy is in compliance with this subsection;

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void;

''(v) verification that the Internet pharmacy expressly and affirmatively agrees to provide the Secretary with the identity of any providers of interactive computer services that provide host services or advertising services for the Internet pharmacy; and

''(vi) assurance that the Internet pharmacy will comply with the requirements under subparagraphs (B) and (C).

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall post in a clear and visible manner, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription from a treating provider.

''(v) A distinctive tamper resistant seal to identify that the Internet pharmacy is licensed.

''(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

''(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

''(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

''(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient before and after the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(III) Submit those reports within 3 days of receipt and the response of the Internet pharmacy to the Food and Drug Administration in a manner determined appropriate by the Secretary.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a valid prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) If the prescription for any drug other than a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) is received from an individual or the treating provider of the individual by mail (including a private carrier), or from the treating provider of the individual by electronic mail, the validity of the prescription shall be confirmed in accordance with all applicable Federal and State laws.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act), the validity of the prescription shall be confirmed with the treating provider as described in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a complete licensing application from an Internet pharmacy under paragraph (2), the Secretary shall—

''(i) assign an identification number to the Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensing application; and

''(iii) if the Internet pharmacy is in compliance with the conditions under paragraph (2), issue a license not later than 60 days after receipt of a licensing application from the Internet pharmacy.

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of electronic methods of submitting to the Secretary a licensing application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensing applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) DATABASE.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a database of the Internet pharmacies licensed under this section.

''(B) AVAILABILITY.—The Secretary shall make the database described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) FEES.—

''(A) IN GENERAL.—

''(i) LICENSING APPLICATION FEE.—The Secretary shall establish a licensing application fee to be paid by all applicants.

''(ii) RENEWAL FEE.—The Secretary shall establish a yearly renewal fee to be paid by all Internet pharmacies licensed under this section.

''(B) COLLECTION.—

''(i) COLLECTION OF LICENSING APPLICATION FEE.—A licensing application fee payable for the fiscal year in which the Internet pharmacy submits a licensing application, as established under subparagraph (C), shall be payable upon the submission to the Secretary of such licensing application.

''(ii) COLLECTION OF RENEWAL FEES.—After the licensing application fee is paid for the first fiscal year of licensure, the yearly renewal fee, as established under subparagraph (C), shall be payable on or before October 1 of each subsequent fiscal year.

''(iii) ONE FEE PER INTERNET PHARMACY.—The licensing application fee and yearly renewal fee shall be paid only once for each Internet pharmacy for a fiscal year in which the fee is payable.

''(C) FEE AMOUNT.—The amount of the licensing application fee and the yearly renewal fee for an Internet pharmacy shall be determined each year by the Secretary based on the anticipated costs to the Secretary of enforcing the requirements of this section in the subsequent fiscal year.

''(D) ANNUAL FEE DETERMINATION.—

''(i) IN GENERAL.—Not later than 60 days before the beginning of each fiscal year beginning after September 30, 2007, the Secretary shall determine the amount of the licensing application fee and the yearly renewal fee for that fiscal year.

''(ii) PUBLICATION OF FEE AMOUNT.—Not later than 60 days before each fiscal year, the Secretary shall publish the amount of the licensing application fee and the yearly renewal fee under this section for that fiscal year and provide for a period of 30 days for the public to provide written comments on the fees.

''(E) USE OF FEES.—The fees collected under this section shall be used, without further appropriation, to carry out this section.

''(F) FAILURE TO PAY FEE.—

''(i) DUE DATE.—A fee payable under this section shall be paid by the date that is 30 days after the date on which the fee is due.

''(ii) FAILURE TO PAY.—If an Internet pharmacy subject to a fee under this section fails to pay the fee by the date specified under clause (i), the Secretary shall not permit the Internet pharmacy to engage in the dispensing of drugs as described under this section until all such fees owed by the Internet pharmacy are paid.

''(G) REPORTS.—Beginning with fiscal year 2008, not later than 60 days after the end of each fiscal year during which licensing application fees are collected under this section, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes—

''(i) implementation of the licensing fee authority during the fiscal year; and

''(ii) the use by the Secretary of the licensing fees collected during the fiscal year for which the report is made.

''(6) SUSPENSION.—

''(A) IN GENERAL.—If the Secretary determines that an Internet pharmacy is engaged in a pattern of violations of any of the requirements of this Act, the Secretary may immediately order the suspension of the license of the Internet pharmacy.

''(B) APPEAL OF SUSPENSION ORDER.—An Internet pharmacy subject to a suspension order under subparagraph (A) may appeal the suspension order to the Secretary. Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall affirm or terminate the order.

''(C) FAILURE TO ACT.—If, during the 30-day period specified in subparagraph (B), the Secretary fails to provide an opportunity for a hearing or to affirm or terminate the order, the order shall be deemed to be terminated.

''(D) NO JUDICIAL REVIEW.—An order under this paragraph shall not be subject to judicial review.

''(7) TERMINATION OF LICENSE.—The Secretary may terminate a license issued under this subsection, after notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that the Internet pharmacy—

''(A) has demonstrated a pattern of noncompliance with this section;

''(B) has made an untrue statement of material fact in its licensing application; or

''(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

''(8) RENEWAL EVALUATION.—

''(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

''(B) EVALUATION OF INTERNET PHARMACIES.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(9) CONTRACT FOR OPERATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

''(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—No provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) or an advertising service provider shall be liable under this section on account of another person's selling or dispensing of a prescription drug, so long as the provider of the interactive computer service or the advertising service provider does not own or exercise corporate control over such person.

''(e) POLICIES AND PROCEDURES REQUIRED TO PREVENT PAYMENTS FOR UNLAWFUL INTERNET PHARMACY REQUESTS.—

''(1) REGULATIONS.—Not later than 180 days after designating a system under subsection (a)(2), the Board shall promulgate regulations that require—

''(A) an operator of a credit card system that is a designated payment system, an operator of an international, national, or local network used to effect a credit transaction, electronic fund transfer, or money transmitting service that is a designated payment system, and an operator of any other designated payment system specified by the Board that is centrally managed and is primarily engaged in the transmission and settlement of credit transactions, electronic transfers, or money transmitting services where at least 1 party to the transaction or transfer is an individual; and

''(B) in the case of a designated payment system, other than a designated payment system described in subparagraph (A), a person described in subsection (a)(2)(B);

to establish policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a designated payment system or the completion of restricted transactions using a designated payment system.

''(2) REQUIREMENTS FOR POLICIES AND PROCEDURES.—In promulgating regulations under paragraph (1), the Board shall—

''(A) identify types of policies and procedures, including nonexclusive examples, that shall be considered to be reasonably designed to identify and reasonably designed to prevent the introduction of a restricted transaction in a designated payment or the completion of restricted transactions using a designated payment system; and

''(B) to the extent practicable, permit any designated payment system, or person described in subsection (a)(2)(B), as applicable, to choose among alternative means of preventing the introduction or completion of restricted transactions.

''(3) NO LIABILITY FOR BLOCKING OR REFUSING TO HONOR RESTRICTED TRANSACTION.—

''(A) IN GENERAL.—A designated payment system, or a person described in subsection (a)(2)(B), that is subject to a regulation or an order issued under this subsection, and any participant in such payment system, that—

''(i) prevents or otherwise refuses to honor restricted transactions, in an effort to implement the policies and procedures required under this subsection or to otherwise comply with this section, shall not be liable to any party for such action; and

''(ii) prevents or otherwise refuses to honor a nonrestricted transaction in an effort to implement the policies and procedures under this subsection or to otherwise comply with this section, shall not be liable to any party for such action.

''(B) COMPLIANCE WITH THIS SUBSECTION.—A person described in subsection (a)(2)(B) meets the requirements of this subsection, if any, if the person relies on and complies with the policies and procedures of a designated payment system of which the person is a member or in which the person is a participant, and such policies and procedures of the designated payment system comply with the requirements of the regulations under paragraph (1)(B).

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—This subsection shall be enforced by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (21 U.S.C. 6805(a)).

''(B) FACTORS TO BE CONSIDERED.—In considering any enforcement action under this subsection against a payment system or person described in subsection (a)(2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

''(i) The extent to which the payment system or person knowingly permits restricted transactions.

''(ii) The history of the payment system or person in connection with permitting restricted transactions.

''(iii) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

''(iv) The feasibility that any specific remedy prescribed can be implemented by the payment system or person without substantial deviation from normal business practice.

''(v) The costs and burdens the specific remedy will have on the payment system or person.

''(f) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).

''(g) TRANSACTIONS PERMITTED.—A designated payment system or person subject to a regulation or an order issued under subsection (e) may engage in transactions with licensed and unlicensed Internet pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with subsection (e). A person subject to a regulation or an order issued under subsection (e) and the agents and employees of that person shall not be found to be in violation of, or liable under, any Federal, State, or other law for engaging in any such transaction.

''(h) RELATION TO STATE LAWS.—No requirement, prohibition, or liability may be imposed on a designated payment system or person subject to a regulation or an order issued under subsection (e) under the laws of any State with respect to any payment transaction by an individual because the payment transaction involves a payment to an Internet pharmacy.

''(i) TIMING OF REQUIREMENTS.—A designated payment system or a person subject to a regulation under subsection (e) shall adopt policies and procedures reasonably designed to comply with any regulations required under subsection (e) not later than 180 days after the date on which such final regulations are issued.''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh)(1) The sale, under section 511, of a drug that is not a prescription drug, the sale of such a prescription drug without a valid prescription from a treating provider, or the ownership or operation of an Internet pharmacy, in violation of section 511.

''(2) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 511.

''(3) The advertisement related to a prescription drug through any media including sales presentation, direct communication (including telephone, facsimile, or electronic mail), by an unlicensed Internet pharmacy.

''(4) The provision of an untrue statement of material fact in the licensing application of an Internet pharmacy.

''(5) For purposes of this subsection, any term used in this subsection that is also used in section 511 shall have the meaning given that term in section 511.''.

(c) LINKS TO UNLICENSED INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 511 relating to an unlicensed Internet pharmacy (as defined in such section 511), the district courts of the United States and the United States courts of the territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, links to a website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 511;

''(C) shall specify the provider to which the relief applies; and

''(D) shall specifically identify the location of the website to be removed or to which access is to be disabled.''.

(d) REGULATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate interim final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SA 1018. Mr. DEMINT (for himself, Mr. INHOFE, Mr. BROWNBACK, Mr. MARTINEZ, Mr. VITTER, and Mr. COBURN) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

In section 214(b)(3)(B) of the bill, insert '', except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified'' before the period at the end.

SA 1019. Mr. CASEY (for himself and Mr. SPECTER) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. ORPHAN DISEASE TREATMENT IN CHILDREN.

(a) FINDING.—The Senate finds that parents of children suffering from rare genetic diseases known as orphan diseases face multiple obstacles in obtaining safe and effective treatment for their children due mainly to the fact that many Food and Drug Administration-approved drugs used in the treatment of orphan diseases in children may not be approved for pediatric indications.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that the Food and Drug Administration should enter into a contract with the Institute of Medicine for the conduct of a study concerning measures that may be taken to improve the likelihood that Food and Drug Administration-approved drugs that are safe and effective in treating children with orphan diseases are made available and affordable for pediatric indications.

SA 1020. Mr. GRASSLEY submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act

to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Strike clause (i) of section 402(j)(3)(A) of the Public Health Service Act, as added by this bill, and insert the following:

''(i) IN GENERAL.—

''(I) REQUIREMENT.—Not later than 90 days after the date of enactment of the Food and Drug Administration Revitalization Act, for all clinical trials (except as provided in subclause (II)), whether federally or privately funded, conducted to test the safety or efficacy (including comparative efficacy), of any drug or device (including those drugs or devices approved or cleared by the Secretary), the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

''(aa) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

''(bb) not later than 30 days after such information becomes publicly available, as applicable.

''(II) EXCEPTION.—The requirement of subclause (I) shall not apply to phase I clinical investigations conducted to test solely the safety of an unapproved drug or unlicensed biological product, or pilot or feasibility studies conducted to confirm the design and operating specifications of an unapproved or not yet cleared medical device.

''(III) VOLUNTARY SUBMISSION.—A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit to the Secretary results information for a clinical trial described in subclause (II).

''(IV) EXPANDED REGISTRY DATA BANK.—Notwithstanding any other provision of law, the clinical trials described in subclause (I) shall be clinical trials of which the results information with respect to such trials is appropriate for adding to the expanded registry data bank, as described in subparagraph (C).

At the end section 402(j)(4) of the Public Health Service Act, as added by this bill, insert the following:

''(F) TRIALS CONDUCTED OUTSIDE OF THE UNITED STATES.—

''(i) IN GENERAL.—With respect to clinical trials described in clause (ii), the responsible party shall submit to the Secretary the information required under this subsection. The Secretary shall ensure that such information and the results of such clinical trials are made available to the public in a timely manner and as soon as practicable after receiving such information. Failure to comply with this paragraph shall be deemed to be a failure to submit information as required under this subsection, and the appropriate remedies and sanctions under this section shall apply.

''(ii) CLINICAL TRIAL DESCRIBED.—A clinical trial is described in this clause if—

''(I) such trial is conducted outside of the United States; and

''(II) the data from such trial is—

''(aa) submitted to the Secretary as part of an application, including a supplemental application, for a drug or device under section 505, 510, 515, or 520 of the Federal Food, Drug, and Cosmetic Act or for the biological product under section 351 of this Act; or

''(bb) used in advertising or labeling to make a claim about the drug or device involved.

''(iii) EXPANDED REGISTRY DATA BANK.—Notwithstanding any other provision of law, the clinical trials described in clause (ii) shall be clinical trials of which the results information with respect to such trials is appropriate for adding to the expanded registry data bank, as described in paragraph (3)(C).

SA 1021. Mrs. CLINTON submitted an amendment intended to be proposed by her to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. NO SUNSET FOR SECTION 505B.

Notwithstanding any provision of this Act, an amendment made by this Act, or any other provision of law, section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) and the authority provided for under such section shall not sunset but shall remain in effect.

SA 1022. Mr. DURBIN (for himself, Mr. ENZI, Mr. KENNEDY, Mr. ALLARD, Mr. KOHL, Ms. CANTWELL, Mr. SCHUMER, Mr. BIDEN, Mr. NELSON of Florida, and Mr. CASEY) proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the bill, insert the following:

TITLE ___—FOOD SAFETY

SEC. __01. FINDINGS.

(a) FINDINGS.—Congress finds that—

(1) the safety and integrity of the United States food supply is vital to the public health, to public confidence in the food supply, and to the success of the food sector of the Nation's economy;

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items;

(3) the task of preserving the safety of the food supply of the United States faces tremendous pressures with regard to—

(A) emerging pathogens and other contaminants and the ability to detect all forms of contamination; and

(B) an increasing volume of imported food from a wide variety of countries; and

(C) a shortage of adequate resources for monitoring and inspection;

(4) the United States is increasing the amount of food that it imports such that —

(A) from 2003 to the present, the value of food imports has increased from $45,600,000,000 to $64,000,000,000; and

(B) imported food accounts for 13 percent of the average Americans diet including 31 percent of fruits, juices, and nuts, 9.5 percent of red meat and 78.6 percent of fish and shellfish; and

(5) the number of full time equivalent Food and Drug Administration employees conducting inspections has decreased from 2003 to 2007.

SEC. __02. ENSURING THE SAFETY OF PET FOOD.

(a) PROCESSING AND INGREDIENT STANDARDS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this title as the ''Secretary''), in consultation with the Association of American Feed Control Officials, and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers, shall by regulation establish—

(1) processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions; and

(2) updated standards for the labeling of pet food that includes nutritional information and ingredient information.

(b) EARLY WARNING SURVEILLANCE SYSTEMS AND NOTIFICATION DURING PET FOOD RECALLS.—Not later than 180 days after the date of enactment of this Act, the Secretary shall by regulation establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. In establishing such system, the Secretary shall—

(1) use surveillance and monitoring mechanisms similar to, or in coordination with, those mechanisms used by the Centers for Disease Control and Prevention to monitor human health, such as the Foodborne Diseases Active Surveillance Network (FoodNet) and PulseNet;

(2) consult with relevant professional associations and private sector veterinary hospitals; and

(3) work with the Health Alert Network and other notification networks to inform veterinarians and relevant stakeholders during any recall of pet food.

SEC. __03. ENSURING EFFICIENT AND EFFECTIVE COMMUNICATIONS DURING A RECALL.

The Secretary shall, during an ongoing recall of human or pet food—

(1) work with companies, relevant professional associations, and other organizations to collect and aggregate information pertaining to the recall;

(2) use existing networks of communication including electronic forms of information dissemination to enhance the quality and speed of communication with the public; and

(3) post information regarding recalled products on the Internet website of the Food and Drug Administration in a consolidated, searchable form that is easily accessed and understood by the public.

SEC. __04. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that assist in improving the safety of fresh and processed produced so that State food safety programs involving the safety of fresh and processed produce and activities conducted by the Secretaries function in a coordinated and cost-effective manner. With the assistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this section. An agreement entered into with a State agency under this subsection may provide for training of State employees.

SEC. __05. ADULTERATED FOOD REGISTRY.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1994, Congress passed the Dietary Supplement Health and Education Act (P.L. 103-417) to provide the Food and Drug Administration with the legal framework to ensure that dietary supplements are safe and properly labeled foods.

(2) In 2006, Congress passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (P.L. 109-462) to establish a mandatory reporting system of serious adverse events for non-prescription drugs and dietary supplements sold and consumed in the United States.

(3) The adverse event reporting system created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act will serve as the early warning system for any potential public health issues associated with the use of these food products.

(4) A reliable mechanism to track patterns of adulteration in food would support efforts by the Food and Drug Administration to effectively target limited inspection resources to protect the public health.

(b) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. ADULTERATED FOOD REGISTRY.

''(a) DEFINITIONS.—In this section:

''(1) IMPORTER.—The term 'importer', with respect to an article of food, means the person who submitted the notice with respect to such article of food under section 801(m).

''(2) RESPONSIBLE PARTY.—The term 'responsible party', with respect to an article of food, means any registered food facility under section 415(a), including those responsible for the manufacturing, processing, packaging or holding of such food for consumption in the United States.

''(3) REPORTABLE ADULTERATED FOOD.—The term 'reportable adulterated food' for purposes of this section means a food that is adulterated or—

''(A) presents a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death as defined in section 7.3(m)(1) of title, Code of Federal Regulations (or any successor regulations); or

''(B) meets the threshold established in section 304(h).

''(b) ESTABLISHMENT.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish within the Food and Drug Administration an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by the Food and Drug Administration after receipt of reports of adulteration, via an electronic portal, from—

''(A) Federal, State, and local public health officials;

''(B) an importer;

''(C) a responsible party; or

''(D) a consumer or other individual.

''(2) REVIEW BY SECRETARY.—The Secretary shall review and determine the validity of the information submitted under paragraph (1) for the purposes of identifying adulterated food, submitting entries to the Adulterated Food Registry, acting under subsection (c), and exercising other existing food safety authorities under the Act to protect the public health.

''(c) ISSUANCE OF AN ALERT BY THE SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue an alert with respect to an adulterated food if the Adulterated Food Registry shows that the food—

''(A) has been associated with repeated and separate outbreaks of illness or has been repeatedly determined to be adulterated; or

''(B) is a reportable adulterated food.

''(2) SCOPE OF ALERT.—An alert under paragraph (1) may apply to a particular food or to food from a particular producer, manufacturer, shipper, growing area, or country, to the extent that elements in subparagraph (A) or (B) of paragraph (1) are associated with the particular food, producer, manufacturer, shipper, growing area, or country.

''(d) SUBMISSION BY A CONSUMER OR OTHER INDIVIDUAL.—A consumer or other individual may submit a report to the Food and Drug Administration using the electronic portal data elements described in subsection (e). Such reports shall be evaluated by the Secretary as specified in subsection (b)(2).

''(e) NOTIFICATION AND REPORTING OF ADULTERATION.—

''(1) DETERMINATION BY RESPONSIBLE PARTY OR IMPORTER.—If a responsible party or importer determines that an article of food it produced, processed, manufactured, distributed, or otherwise handled is a reportable adulterated food, the responsible party shall provide the notifications described under paragraph (2).

''(2) NOTIFICATION OF ADULTERATION.—

''(A) IN GENERAL.—Not later than 5 days after a responsible party or importer receives a notification, the responsible party or importer, as applicable, shall review whether the food referenced in the report described in paragraph (1) is a reportable adulterated food.

''(B) NOTIFICATION.—If a determination is made by such responsible party or importer that the food is a reportable adulterated food, such responsible party or importer shall, no later than 5 days after such determination is made, notify other responsible parties directly linked in the supply chain to which and from which the article of reportable adulterated food was transferred.

''(3) SUBMISSION OF REPORTS TO THE FOOD AND DRUG ADMINISTRATION BY A RESPONSIBLE PARTY OR IMPORTER.—The responsible party or importer, as applicable, shall submit a report to the Food and Drug Administration through the electronic portal using the data elements described in subsection (f) not later than 2 days after a responsible party or importer—

''(A) makes a notification under paragraph (2)(B); or

''(B) determines that an article of food it produced, processed, manufactured, distributed, imported, or otherwise handled is a reportable adulterated food, except that if such adulteration was initiated with such responsible party or importer, was detected prior to any transfer of such article of food, and was destroyed, no report is necessary.

''(f) DATA ELEMENTS IN THE REGISTRY.—A report submitted to the Food and Drug Administration electronic portal under subsection (e) shall include the following data elements:

''(1) Contact information for the individual or entity submitting the report.

''(2) The date on which an article of food was determined to be adulterated or suspected of being adulterated.

''(3) A description of the article of food including the quantity or amount.

''(4) The extent and nature of the adulteration.

''(5) The disposition of the article.

''(6) Product information typically found on packaging including product codes, use by dates, and names of manufactures or distributors.

''(7) Information about the place of purchase or process by which the consumer or other individual acquired the article of adulterated food.

''(8) In the case of a responsible party or an importer, the elements required for the registration of food facilities under section 415(a).

''(9) The contact information for parties directly linked in the supply chain and notified under subsection (e)(2).

''(10) In the case of an importer, the elements required for the prior notice of imported food shipments under section 801(m).

''(g) MAINTENANCE AND INSPECTION OF RECORDS.—The responsible person or importer shall maintain records related to each report received, notification made, and report submitted to the Food and Drug Administration under this section and permit inspection of such records as provided for in section 414. Such records shall also be made available during an inspection under section 704.

''(h) REQUEST FOR INFORMATION.—Section 552 of title 5, United States Code, shall apply to any request for information regarding a record in the Adulterated Food Registry.

''(i) HOMELAND SECURITY NOTIFICATION.—If, after receiving a report under subsection (e), the Secretary suspects such food may have been deliberately adulterated, the Secretary shall immediately notify the Secretary of Homeland Security. The Secretary shall make the data in the Adulterated Imported Food Registry available to the Secretary of Homeland Security.''.

(c) DEFINITION.—Section 201(ff) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff)) is amended by striking ''section 201(g)'' and inserting ''sections 201(g) and 417''.

(d) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end the following:

''(kk) The failure to provide a report as required under section 417(e)(3).

''(ll) The falsification a report as required under section 417(e)(3).''.

(e) SUSPECTED FOOD ADULTERATION REGULATIONS.—The Secretary shall, within 180 days of enactment of this Act, promulgate regulations that establish standards and thresholds by which importers and responsible parties shall be required and consumers may be able to, under section 417 of the Federal Food, Drug, and Cosmetic Act (as added by this section)—

(1) report instances of suspected reportable adulteration of food to the Food and Drug Administration for possible inclusion in the Adulterated Food Registry after evaluation of such report; and

(2) notify, in keeping with subsection (e)(2) of such section 417, other responsible parties directly linked in the supply chain, including establishments as defined in section 415(b) of such Act.

(f) EFFECTIVE DATE.—The requirements of section 417(e) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall become effective 180 days after the date of enactment of this Act.

SEC. _06. SENSE OF THE SENATE.

It is the sense of the Senate that—

(1) it is vital for Congress to provide the Food and Drug Administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply of the United States;

(2) additional inspectors are required to improve the Food and Drug Administration's ability to safeguard the food supply of the United States;

(3) because of the increasing volume of international trade in food products the Secretary of Health and Human Services should make it a priority to enter into agreements with the trading partners of the United States with respect to food safety; and

(4) the Senate should work to develop a comprehensive response to the issue of food safety.

SEC. __07. ANNUAL REPORT TO CONGRESS.

The Secretary shall, on an annual basis, submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report that includes, with respect to the preceding 1-year period—

(1) the number and amount of food products regulated by the Food and Drug Administration imported into the United States, aggregated by country and type of food;

(2) a listing of the number of Food and Drug Administration inspectors of imported food products referenced in paragraph (1) and the number of Food and Drug Administration inspections performed on such products; and

(3) aggregated data on the findings of such inspections, including data related to violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.), and enforcement actions used to follow-up on such findings and violations.

SEC. __08. RULE OF CONSTRUCTION.

Nothing in this title (or an amendment made by this title) shall be construed to affect—

(1) the regulation of dietary supplements under the Dietary Supplement Health and Education Act; or

(2) the adverse event reporting system for dietary supplements created under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

SEC. __09. AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this title (and the amendments made by this title) such sums as may be necessary.

SA 1023. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. STUDY ON FOOD INSPECTION AND SAFETY USER FEES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the feasibility of instituting a user fee program for food inspections and food safety that incorporates lessons learned from the user fee program for prescription drugs under chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) and that is designed to increase the resources and capabilities of the Food and Drug Administration to safeguard the food supply of the United States.

(b) REPORT TO CONGRESS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that—

(1) describes the findings of the study conducted under subsection (a); and

(2) includes—

(A) any recommendations for legislation related to such findings; and

(B) provides details, with respect to such recommended legislation, regarding—

(i) the expected revenues for the Food and Drug Administration;

(ii) the expected costs to the private sector, categorized by industry; and

(iii) any other relevant information.

SA 1024. Mr. SALAZAR submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PROHIBITION OF REORGANIZATION PLAN PENDING REVIEW.

(a) IN GENERAL.—The Commissioner of Food and Drugs may not implement a reorganization plan that reduces or consolidates the number of laboratory facilities currently in operation within the Office of Regulatory Affairs of the Food and Drug Administration pending a comprehensive review of the reorganization plan by the Comptroller General of the United States to determine—

(1) the impact of the reorganization on the mission of the Food and Drug Administration to ensure that foods, cosmetics, and medical products are safe, effective, and properly promoted and labeled;

(2) the projected cost savings; and

(3) the projected operational efficiencies.

(b) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General of the United States shall issue a report on the impact of the reorganization plan described in subsection (a).

SA 1025. Mr. SCHUMER (for himself, Mrs. CLINTON, Mr. ENZI, Mr. HATCH, and Mr. KENNEDY) proposed an amendment to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; as follows:

At the end of the bill, add the following:

SEC. ___. SENSE OF THE SENATE WITH RESPECT TO FOLLOW-ON BIOLOGICS.

(a) FINDINGS.—The Senate finds the following:

(1) The Food and Drug Administration has stated that it requires legislative authority to review follow-on biologics.

(2) Business, consumer, and government purchasers require competition and choice to ensure more affordable prescription drug options.

(3) Well-constructed policies that balance the needs of innovation and affordability have broad bipartisan support.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) legislation should be enacted to—

(A) provide the Food and Drug Administration with the authority and flexibility to approve biopharmaceuticals subject to an abbreviated approval pathway;

(B) ensure that patient safety remains paramount in the system;

(C) establish a regulatory pathway that is efficient, effective, and scientifically-grounded and that also includes measures to ensure timely resolution of patent disputes; and

(D) provide appropriate incentives to facilitate the research and development of innovative biopharmaceuticals.

SA 1026. Mr. FEINGOLD submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ___. PUBLICATION OF ANNUAL REPORTS.

(a) IN GENERAL.—The Commissioner on Food and Drugs shall annually submit to Congress and publish on the Internet website of the Food and Drug Administration, a report concerning the results of the Administration's pesticide residue monitoring program, that includes—

(1) information and analysis similar to that contained in the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'' as released in June of 2005;

(2) based on an analysis of previous samples, an identification of products or countries (for imports) that require special attention and additional study (including details on the plans for such additional studies), including in the initial report (and subsequent reports as determined necessary) the results and analysis of the Ginseng Dietary Supplements Special Survey as described on page 13 of the report entitled ''Food and Drug Administration Pesticide Program Residue Monitoring 2003'';

(3) information on the relative number of interstate and imported shipments of each tested commodity that were sampled, including recommendations on whether sampling is statistically significant, provides confidence intervals or other related statistical information, and whether the number of samples should be increased and the details of any plans to provide for such increase; and

(4) a description of whether certain commodities are being improperly imported as another commodity, including a description of additional steps that are being planned to prevent such smuggling.

(b) INITIAL REPORTS.—Annual reports under subsection (a) for fiscal years 2004 through 2006 may be combined into a single report, by not later than June 1, 2008, for purposes of publication under subsection (a). Thereafter such reports shall be completed by June 1 of each year for the data collected for the year that was 2-years prior to the year in which the report is published.

(c) MEMORANDUM OF UNDERSTANDING.—The Commissioner of Food and Drugs, the Administrator of the Food Safety and Inspection Service, and the head of the Agricultural Marketing Service shall enter into a memorandum of understanding to permit inclusion of data in the reports under subsection (a) relating to testing carried out by the Food Safety and Inspection Service and the Agricultural Marketing Service on meat, poultry, eggs, and certain raw agricultural products, respectively.

SA 1027. Mr. DURBIN submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

TITLE ___—FOOD SAFETY

SEC. ___. FOOD SAFETY FOR HUMANS AND PETS.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by adding at the end the following:

''SEC. 417. NOTIFICATION AND RECALL.

''(a) NOTICE TO SECRETARY OF VIOLATION.—

''(1) IN GENERAL.—A person that has reason to believe that any food introduced into or in interstate commerce, or held for sale (whether or not the first sale) after shipment in interstate commerce, may be in violation of this Act shall immediately notify the Secretary of the identity and location of the food.

''(2) MANNER OF NOTIFICATION.—Notification under paragraph (1) shall be made in such manner and by such means as the Secretary may require by regulation.

''(b) RECALL AND CONSUMER NOTIFICATION; VOLUNTARY ACTIONS.—If the Secretary determines that food is in violation of this Act when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce and that there is a reasonable probability that the food, if consumed, would present a threat to public health, as determined by the Secretary, the Secretary shall give the appropriate persons (including the manufacturers, importers, distributors, or retailers of the food) an opportunity to—

''(1) cease distribution of the food;

''(2) notify all persons—

''(A) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(B) to which the food has been distributed, transported, or sold, to immediately cease distribution of the food;

''(3) recall the food;

''(4) in conjunction with the Secretary, provide notice of the finding of the Secretary—

''(A) to consumers to whom the food was, or may have been, distributed; and

''(B) to State and local public health officials; or

''(5) take any combination of the measures described in this paragraph, as determined by the Secretary to be appropriate in the circumstances.

''(c) CIVIL AND CRIMINAL PENALTIES.—

''(1) CIVIL SANCTIONS.—

''(A) CIVIL PENALTY.—Any person that commits an act that violates the notification and recall standards under subsection (b) (including a regulation promulgated or order issued under this Act) may be assessed a civil penalty by the Secretary of not more than $10,000 for each such act.

''(B) SEPARATE OFFENSE.—Each act described in subparagraph (A) and each day during which that act continues shall be considered a separate offense.

''(2) OTHER REQUIREMENTS.—

''(A) WRITTEN ORDER.—The civil penalty described in paragraph (1) shall be assessed by the Secretary by a written order, which shall specify the amount of the penalty and the basis for the penalty under subparagraph (B) considered by the Secretary.

''(B) AMOUNT OF PENALTY.—Subject to paragraph (1)(A), the amount of the civil penalty shall be determined by the Secretary, after considering—

''(i) the gravity of the violation;

''(ii) the degree of culpability of the person;

''(iii) the size and type of the business of the person; and

''(iv) any history of prior offenses by the person under this Act.

''(C) REVIEW OF ORDER.—The order may be reviewed only in accordance with subsection (d).

''(3) EXCEPTION.—No person shall be subject to the penalties of this subsection—

''(A) for having received, proffered, or delivered in interstate commerce any food, if the receipt, proffer, or delivery was made in good faith, unless that person refuses to furnish (on request of an officer or employee designated by the Secretary)—

''(i) the name, address and contact information of the person from whom that person purchased or received the food;

''(ii) copies of all documents relating to the person from whom that person purchased or received the food; and

''(iii) copies of all documents pertaining to the delivery of the food to that person; or

''(B) if that person establishes a guaranty signed by, and containing the name and address of, the person from whom that person received in good faith the food, stating that the food is not adulterated or misbranded within the meaning of this Act.

''(d) JUDICIAL REVIEW.—

''(1) IN GENERAL.—An order assessing a civil penalty under subsection (c) shall be a final order unless the person—

''(A) not later than 30 days after the effective date of the order, files a petition for judicial review of the order in the United States court of appeals for the circuit in which that person resides or has its principal place of business or the United States Court of Appeals for the District of Columbia; and

''(B) simultaneously serves a copy of the petition by certified mail to the Secretary.

''(2) FILING OF RECORD.—Not later than 45 days after the service of a copy of the petition under paragraph (1)(B), the Secretary shall file in the court a certified copy of the administrative record upon which the order was issued.

''(3) STANDARD OF REVIEW.—The findings of the Secretary relating to the order shall be set aside only if found to be unsupported by substantial evidence on the record as a whole.

''(e) COLLECTION ACTIONS FOR FAILURE TO PAY.—

''(1) IN GENERAL.—If any person fails to pay a civil penalty assessed under subsection (c) after the order assessing the penalty has become a final order, or after the court of appeals described in subsection (d) has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General, who shall institute in a United States district court of competent jurisdiction a civil action to recover the amount assessed.

''(2) LIMITATION ON REVIEW.—In a civil action under paragraph (1), the validity and appropriateness of the order of the Secretary assessing the civil penalty shall not be subject to judicial review.

''(f) PENALTIES PAID INTO ACCOUNT.—The Secretary—

''(1) shall deposit penalties collected under this section in an account in the Treasury; and

''(2) may use the funds in the account, without further appropriation or fiscal year limitation—

''(A) to carry out enforcement activities under food safety law; or

''(B) to provide assistance to States to inspect retail commercial food establishments, such as an establishment that holds, stores, or transports food or food ingredients, or other food or firms under the jurisdiction of State food safety programs.

''(g) DISCRETION OF THE SECRETARY TO PROSECUTE.—Nothing in this section or section 418 requires the Secretary to report for prosecution, or for the commencement of an action, the violation of this Act in a case in which the Secretary finds that the public interest will be adequately served by the assessment of a civil penalty under this section.

''(h) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section may be in addition to, and not exclusive of, other remedies that may be available.

''SEC. 418. MANDATORY RECALL ACTION.

''(a) MANDATORY ACTIONS.—If a person referred to in section 417(b) refuses to or does not adequately carry out the actions described in that section within the time period and in the manner prescribed by the Secretary, the Secretary shall—

''(1) have authority to control and possess the food, including ordering the shipment of the food from a food establishment, such as an establishment that holds, stores, or transports food or food ingredients, to the Secretary—

''(A) at the expense of such food establishment; or

''(B) in an emergency (as determined by the Secretary), at the expense of the Secretary; and

''(2) by order, require, as the Secretary determines to be necessary, the person to immediately—

''(A) cease distribution of the food; and

''(B) notify all persons—

''(i) processing, distributing, or otherwise handling the food to immediately cease such activities with respect to the food; or

''(ii) if the food has been distributed, transported, or sold, to immediately cease distribution of the food.

''(b) NOTIFICATION TO CONSUMERS BY SECRETARY.—The Secretary shall, as the Secretary determines to be necessary, provide notice of the finding of the Secretary under paragraph (1)—

''(1) to consumers to whom the food was, or may have been, distributed; and

''(2) to State and local public health officials.

''(c) NONDISTRIBUTION BY NOTIFIED PERSONS.—A person that processes, distributes, or otherwise handles the food, or to which the food has been distributed, transported, or sold, and that is notified under section 417(b)(2) or subsection (a)(2)(B) of this section shall immediately cease distribution of the food.

''(d) AVAILABILITY OF RECORDS TO SECRETARY.—Each person referred to in section 417 that processed, distributed, or otherwise handled food shall make available to the Secretary information necessary to carry out this subsection, as determined by the Secretary, regarding—

''(1) persons that processed, distributed, or otherwise handled the food; and

''(2) persons to which the food has been transported, sold, distributed, or otherwise handled.

''(e) INFORMAL HEARINGS ON ORDERS.—

''(1) IN GENERAL.—The Secretary shall provide any person subject to an order under subsection (a) with an opportunity for an informal hearing, to be held as soon as practicable but not later than 2 business days after the issuance of the order.

''(2) SCOPE OF THE HEARING.—In a hearing under paragraph (1), the Secretary shall consider the actions required by the order and any reasons why the food that is the subject of the order should not be recalled.

''(f) POST-HEARING RECALL ORDERS.—

''(1) AMENDMENT OF ORDER.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that there is a reasonable probability that the food that is the subject of an order under subsection (a), if consumed, would present a threat to the public health, the Secretary, as the Secretary determines to be necessary, may—

''(A) amend the order to require recall of the food or other appropriate action;

''(B) specify a timetable in which the recall shall occur;

''(C) require periodic reports to the Secretary describing the progress of the recall; and

''(D) provide notice of the recall to consumers to whom the food was, or may have been, distributed.

''(2) VACATION OF ORDERS.—If, after providing an opportunity for an informal hearing under subsection (e), the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary shall vacate the order.

''(g) REMEDIES NOT EXCLUSIVE.—The remedies provided in this section shall be in addition to, and not exclusive of, other remedies that may be available.''.

SA 1028. Mr. ROCKEFELLER (for himself, Mr. SCHUMER, Mr. LEAHY, Mr.

KOHL, and Ms. STABENOW) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the end of the bill, add the following:

SEC. ___. PROHIBITION OF AUTHORIZED GENERICS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this Act, is further amended by adding at the end the following:

''(s) PROHIBITION OF AUTHORIZED GENERIC DRUGS.—

''(1) IN GENERAL.—Notwithstanding any other provision of this Act, no holder of a new drug application approved under subsection (c) shall manufacture, market, sell, or distribute an authorized generic drug, direct or indirectly, or authorize any other person to manufacture, market, sell, or distribute an authorized generic drug.

''(2) AUTHORIZED GENERIC DRUG.—For purposes of this subsection, the term 'authorized generic drug'—

''(A) means any version of a listed drug (as such term is used in subsection (j)) that the holder of the new drug application approved under subsection (c) for that listed drug seeks to commence marketing, selling, or distributing, directly or indirectly, after receipt of a notice sent pursuant to subsection (j)(2)(B) with respect to that listed drug; and

''(B) does not include any drug to be marketed, sold, or distributed—

''(i) by an entity eligible for exclusivity with respect to such drug under subsection (j)(5)(B)(iv); or

''(ii) after expiration or forfeiture of any exclusivity with respect to such drug under such subsection (j)(5)(B)(iv).''.

SA 1029. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

Beginning on page 138 strike line 5 and all that follows through line 10 on page 142 and insert the following:

''(x) specify a process for annual Board review of the operations of the Foundation;

''(xi) establish specific duties of the Executive Director; and

''(xii) establish specific policies to safeguard the Federal Government's patent rights in inventions made with Federal assistance through the Foundation;

''(B) prioritize and provide overall direction to the activities of the Foundation;

''(C) evaluate the performance of the Executive Director; and

''(D) carry out any other necessary activities regarding the functioning of the Foundation.

''(3) TERMS AND VACANCIES.—

''(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.

''(B) VACANCY.—Any vacancy in the membership of the Board—

''(i) shall not affect the power of the remaining members to execute the duties of the Board; and

''(ii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

''(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

''(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

''(4) COMPENSATION.—Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

''(e) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

''(f) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, shall be subject to the provisions of such section, and shall be considered a nonprofit organization for purpose of section 201(i) of title 35, United States Code.

''(g) EXECUTIVE DIRECTOR.—

''(1) IN GENERAL.—The Board shall appoint an Executive Director who shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

''(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

''(h) ADMINISTRATIVE POWERS.—In carrying out this subchapter, the Board, acting through the Executive Director, may—

''(1) adopt, alter, and use a corporate seal, which shall be judicially noticed;

''(2) hire, promote, compensate, and discharge 1 or more officers, employees, and agents, as may be necessary, and define their duties;

''(3) prescribe the manner in which—

''(A) real or personal property of the Foundation is acquired, held, and transferred;

''(B) general operations of the Foundation are to be conducted; and

''(C) the privileges granted to the Board by law are exercised and enjoyed;

''(4) with the consent of the applicable executive department or independent agency, use the information, services, and facilities of such department or agencies in carrying out this section;

''(5) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

''(6) hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation under subsection (i);

''(7) enter into such other contracts, leases, cooperative agreements, and other transactions as the Board considers appropriate to conduct the activities of the Foundation, except that Federal rights in patented inventions made with Federal assistance shall be preserved;

''(8) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this subchapter;

''(9) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees, except that Federal rights in patented inventions made with Federal assistance shall be preserved;

SA 1030. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 171, between lines 18 and 19, insert the following:

''(C) ADDITIONAL CERTIFICATION.—At the time of the submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act or section 351 of the Public Health Service Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of sections 201 through 212 of title 35, United States Code, and any other provision of Federal law relating to Federal rights in patented inventions made with Federal Government assistance, have been met, including, where applicable, the requirement under section 201(f) of such title that the benefits of such inventions be made available to the public on reasonable terms, including price.''.

SA 1031. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 171, line 16, insert before the period the following: '', and that any patent filed or that will be filed contains a statement specifying that the invention was made with Federal Government support and that the Federal Government has certain rights in it, if such a statement is otherwise required by law''.

SA 1032. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 156, between lines 2 and 3, insert the following:

''(VII) The rights of the Federal Government in the drug or device that is the subject of the clinical trial.''.

SA 1033. Mr. SANDERS submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

On page 145, between lines 11 and 12, insert the following:

''(n) PROTECTING FEDERAL RIGHTS IN PATENTED INVENTIONS DEVELOPED WITH FEDERAL GOVERNMENT ASSISTANCE.—Any invention developed by the Foundation or with the funds of the Foundation shall be considered a subject invention for purposes of section 201(e) of title 35, United States Code.''.

AUTHORITY FOR COMMITTEES TO MEET

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Commerce, Science, and Transportation be authorized to hold a hearing during the session of the Senate on Wednesday, May 2, 2007, at 4 p.m., in room 253 of the Russell Senate Office Building. The purpose of the hearing is to hear the views of the five most recent U.S. Nobel Laureates on the state of the country's scientific enterprise and the importance of scientific investment.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON ENERGY AND NATURAL RESOURCES

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Energy and Natural Resources be authorized to hold a business meeting during the session of the Senate on Wednesday, May 2, 2007, at 10 a.m. in room SD–366 of the Dirksen Senate Office Building.

The purpose of the business meeting is to consider the nomination of Stephen J. Isakowitz to be the Chief Financial Officer of the Department of Energy, and the draft of an original bill, which is drawn from the text of the following bills:

S. 731—A bill to develop a methodology for, and complete, a national assessment of geological storage capacity for carbon dioxide, and for other purposes.

S. 962—A bill to amend the Energy Policy Act of 2005 to reauthorize and improve the carbon capture and storage research, development, and demonstration program of the Department of Energy and for other purposes.

S. 987—A bill to enhance the energy security of the United States by promoting biofuels, and for other purposes.

S. 1115—A bill to promote the efficient use of oil, natural gas, and electricity, reduce oil consumption, and heighten energy efficiency standards for consumer products and industrial equipment, and for other purposes.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FINANCE

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on Wednesday, May 2, 2007, at 10 a.m., in 215 Dirksen Senate Office Building, to hear testimony on ''The Medicare Prescription Drug Benefit: Monitoring Early Experiences.''

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON THE JUDICIARY

Mr. BROWN. Mr. President, I ask unanimous consent that the Senate Committee on the Judiciary Subcommittee on Terrorism, Technology and Homeland Security be authorized to meet to conduct a hearing on ''Interrupting Terrorist Travel: Strengthening the Security of International Travel Documents'' for Wednesday, May 2, 2007 at 10 a.m. in Dirksen Senate Office Building Room 226.

Panel I: Andrew Simkin, Director of Fraud Prevention Programs, Bureau of Consular Affairs, Department of State, Washington, DC; Patrick Donovan, Assistant Director for Domestic Operations and Acting Director of Diplomatic Security for Counter Measures, Diplomatic Security, Department of State, Washington, DC; Michael P. Everitt, Unit Chief, Forensic Documents Laboratory, Immigration and Customs Enforcement, Department of Homeland Security, Washington, DC; Paul Morris, Executive Director. Admissibility Requirements and Migration Control Office of Field Operations, U.S. Customs and Border Protection Washington, DC.

Panel II: The Honorable Ronald K. Noble, Secretary General of Interpol, Lyon, France; Clark Kent Ervin, Director of Homeland Security, Aspen Institute, Former Inspector General of Department of Homeland Defense and Author of ''Open Target: Where America is Vulnerable to Attack,'' Washington, DC; Brian Zimmer, Senior Associate, Kelly, Anderson & Associates Inc., Former Senior Investigator, Committee on the Judiciary, U.S. House of Representatives, Washington, DC.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

Mr. BROWN. Mr. President, I ask unanimous consent that the Committee on Small Business and Entrepreneurship be authorized to meet during the session of the Senate for a roundtable entitled ''SBA Reauthorization: Small Business Loan Programs,'' on Wednesday, May 2, 2007, beginning at 10 a.m. in room 428A of the Russell Senate Office Building.

The PRESIDING OFFICER. Without objection, it is so ordered.

SPECIAL COMMITTEE ON AGING

Mr. BROWN. Mr. President, I ask unanimous consent that the Special Committee on Aging be authorized to meet on Wednesday, May 2, 2007 from 10:30 a.m.–12:30 p.m. in Dirksen 628 for the purpose of conducting a hearing concerning Nursing Home Reform.

The PRESIDING OFFICER. Without objection, it is so ordered.

SUBCOMMITTEE ON STRATEGIC FORCES

Mr. BROWN. Mr. President, I ask unanimous consent that the Subcommittee on Strategic Forces of the Committee on Armed Services be authorized to meet in open session during the session of the Senate on Wednesday, May 2, 2007, at 2:30 p.m., to receive testimony on Department of Energy Atomic Energy Defense programs in review of the defense authorization request for fiscal year 2008.

The PRESIDING OFFICER. Without objection, it is so ordered.

PRIVILEGES OF THE FLOOR

Mr. ALLARD. Mr. President, I ask unanimous consent that Leigh Ann Ross, a fellow in the office of Senator THAD COCHRAN, be granted the privilege of the floor for the duration of Senate debate on the 2007 FDA reauthorization bill.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, I ask unanimous consent that Thomas Kraus, an intern on my staff, be granted floor privileges for the remainder of the debate on the Food and Drug Administration Revitalization Act of 2007.

The ACTING PRESIDENT pro tempore. Without objecting it is so ordered.

COMMENDATION OF PUBLIC SERVANTS

Mr. MENENDEZ. Madam President, I ask unanimous consent that the Homeland Security/Governmental Affairs Committee be discharged from further consideration of S. Res. 150, and that the Senate then proceed to its consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the resolution by title.

The legislative clerk read as follows:

A resolution (S. Res. 150) expressing the sense of the Senate that public servants should be commended for their dedication and continued service to the Nation during Public Service Recognition Week, May 7 through 13, 2007.

There being no objection, the Senate proceeded to consider the resolution.

Mr. MENENDEZ. Madam President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, the motion to reconsider be laid upon the table; that any statements relating thereto be printed in the RECORD, without further intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The resolution (S. Res. 150) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, reads as follows:

S. RES. 150

Whereas Public Service Recognition Week provides an opportunity to recognize the important contributions of public servants and honor the diverse men and women who meet the needs of the Nation through work at all levels of government;

Whereas millions of individuals work in government service in every city, county, and State across America and in hundreds of cities abroad;

Whereas public service is a noble calling involving a variety of challenging and rewarding professions;

Whereas Federal, State, and local governments are responsive, innovative, and effective because of the outstanding work of public servants;

Whereas the United States of America is a great and prosperous Nation, and public service employees contribute significantly to that greatness and prosperity;

Whereas the Nation benefits daily from the knowledge and skills of these highly trained individuals;

Whereas public servants—

(1) provide vital strategic support functions to our military and serve in the National Guard and Reserves;

(2) fight crime and fire;

(3) ensure equal access to secure, efficient, and affordable mail service;

(4) deliver social security and medicare benefits;

(5) fight disease and promote better health;

(6) protect the environment and the Nation's parks;

(7) enforce laws guaranteeing equal employment opportunities and healthy working conditions;

(8) defend and secure critical infrastructure;

(9) help the Nation recover from natural disasters and terrorist attacks;

(10) teach and work in our schools and libraries;

(11) develop new technologies and explore the earth, moon, and space to help improve our understanding of how our world changes;

(12) improve and secure our transportation systems;

(13) keep the Nation's economy stable; and

(14) defend our freedom and advance United States interests around the world;

Whereas members of the uniformed services and civilian employees at all levels of government make significant contributions to the general welfare of the United States, and are on the front lines in the fight against terrorism and in maintaining homeland security;

Whereas public servants work in a professional manner to build relationships with other countries and cultures in order to better represent America's interests and promote American ideals;

Whereas public servants alert Congress and the public to government waste, fraud, abuse, and dangers to public health;

Whereas the men and women serving in the Armed Forces of the United States, as well as those skilled trade and craft Federal employees who provide support to their efforts, are committed to doing their jobs regardless of the circumstances, and contribute greatly to the security of the Nation and the world;

Whereas public servants have bravely fought in armed conflict in defense of this Nation and its ideals and deserve the care and benefits they have earned through their honorable service;

Whereas government workers have much to offer, as demonstrated by their expertise and innovative ideas, and serve as examples by passing on institutional knowledge to train the next generation of public servants;

Whereas May 7 through 13, 2007, has been designated Public Service Recognition Week to honor America's Federal, State, and local government employees; and

Whereas Public Service Recognition Week is celebrating its 23rd anniversary through job fairs, student activities, and agency exhibits: Now, therefore, be it

Resolved, That the Senate—

(1) commends public servants for their outstanding contributions to this great Nation during Public Service Recognition Week and throughout the year;

(2) salutes their unyielding dedication and spirit for public service;

(3) honors those government employees who have given their lives in service to their country;

(4) calls upon a new generation to consider a career in public service as an honorable profession; and

(5) encourages efforts to promote public service careers at all levels of government.

ORDERS FOR THURSDAY, MAY 3, 2007

Mr. MENENDEZ. Madam President, I ask unanimous consent that when the Senate completes its business today, it stand adjourned until 9:30 a.m., Thursday, May 3; that on Thursday, following the prayer and the pledge, the Journal of proceedings be approved to date, the morning hour be deemed to have expired, and the time for the two leaders be reserved for their use later in the day; that the Senate then resume consideration of S. 1082 and there be an hour of debate prior to a vote on the motion to invoke cloture on the Dorgan amendment No. 990, with the time equally divided and controlled between Senator DORGAN and the Republican leader or his designee; that upon the use or yielding back of the time, the Senate proceed to vote on that motion to invoke cloture; and that Members have until 10 a.m. to file any second-degree amendments.

The PRESIDING OFFICER. Without objection, it is so ordered.

ADJOURNMENT UNTIL 9:30 A.M. TOMORROW

Mr. MENENDEZ. Madam President, if there is no further business today, I ask unanimous consent that the Senate stand adjourned under the previous order.

There being no objection, the Senate, at 6:24 p.m., adjourned until Thursday, May 3, 2007, at 9:30 a.m.